

§ 51.351 or § 51.352 shall be met using an evaluation date (rounded to the nearest January for carbon monoxide and July for hydrocarbons) seven years after the date EPA notifies the state that it is in violation of the ozone or CO standard or any earlier date specified in the state plan. Emission standards for vehicles subject to an IM240 test may be phased in during the program but full standards must be in effect for at least one complete test cycle before the end of the 5-year period. All other requirements shall take effect within 24 months of the date EPA notifies the state that it is in violation of the ozone or CO standard or any earlier date specified in the state plan. The phase-in allowances of § 51.373(c) of this subpart shall not apply.

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40 CFR Part 69

[FRL-5296-9]

Special Exemptions From Requirements of the Clean Air Act for the Territory of Guam

AGENCY: Environmental Protection Agency ("EPA").

ACTION: Direct final rulemaking.

SUMMARY: On July 14, 1995, the Governor of Guam filed a petition ("Petition") with the Administrator seeking a waiver of certain Clean Air Act ("CAA") requirements which apply to Guam Power Authority ("GPA"). The Petition was filed under Section 325(a) of the CAA. The waiver will help to ease a severe energy emergency on Guam. Based upon the information in the Petition and supplementary information from GPA and the Guam Environmental Protection Agency ("GEPA"), EPA is granting the waiver requested. EPA finds that there is good cause for a direct final rulemaking and that notice and public procedures are impracticable, unnecessary, and contrary to the public interest.

The waiver allows, with certain conditions, one baseload diesel electric generating facility to operate at the Cabras Power Plant prior to the receipt of a final Prevention of Significant Deterioration ("PSD") permit by GPA. The waiver also allows the construction, but not operation, of a second baseload diesel unit at the Cabras Power Plant prior to GPA's receipt of a final PSD permit.

EFFECTIVE DATE: This direct final rule is effective September 18, 1995.

FOR FURTHER INFORMATION CONTACT: Norman Lovelace, Chief, Office of Pacific Islands and Native American Programs (E-4), Office of External Affairs, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, California 94105. Telephone: (415) 744-1599.

SUPPLEMENTARY INFORMATION:

Background

The Petition was submitted by Governor Gutierrez of Guam to the Administrator of EPA in a letter dated July 14, 1995. It is accompanied by supporting documentation, including newspaper accounts describing traffic safety, water supply, and political problems caused by the significant electrical energy shortage on Guam. The Petition incorporates an air quality analysis, based upon computer modeling, which demonstrates the effects of the waiver upon air quality, particularly in the offshore direction, from the generating facilities involved.

The Petition seeks a waiver of certain CAA requirements for the operation and construction by GPA of two baseload diesel electric generators. Both units are part of the Cabras Power Plant. The first facility involved is designated as Cabras Unit No. 3. This forty megawatt diesel generator was constructed, pursuant to 40 CFR 69.11(a)(1), prior to GPA's receipt of a final PSD permit. (This unit is designated Cabras Diesel No. 1 in 40 CFR 69.11(a)(1). Its designation has been changed since the 1993 promulgation of that rule.) The Petition asks EPA to waive CAA requirements as necessary to allow operation of Cabras Unit No. 3, subject to conditions, prior to receipt of a final PSD permit by GPA.

The waiver describes two conditions accompanying the operation of Cabras Unit No. 3. First, during operations under the waiver a lower sulfur fuel oil will be fired in the Cabras Power Plant and in the adjacent Piti Power Plant during certain periods. These power plants operate under a fuel switching intermittent control strategy, and the sulfur-in-fuel reduction in the waiver application applies to operations under offshore wind conditions. Second, the waiver will last only until August 15, 1996, or until issuance of a final PSD permit to GPA for this unit, whichever occurs first.

The Petition also seeks a waiver of CAA requirements as necessary to allow GPA to construct a second forty megawatt baseload unit at the Cabras Power Plant. This facility is designated as Cabras Unit No. 4. The waiver application seeks to allow construction of Cabras Unit No. 4 prior to a receipt

by GPA of a PSD permit. Cabras Unit No. 4 will not operate prior to receipt of final PSD permit.

Guam has experienced a longstanding shortage of electrical energy, repeatedly leading to rotating blackouts of areas of the island. The background to this energy shortage is described in the 1993 waiver proceeding before EPA. 50 FR 15579, 15580. The Petition describes how the 1993 energy shortage has continued despite a substantial capital development program by GPA, and in some respects has grown worse. The energy shortage was created originally because of very rapid growth in energy demand due to increased residential electrical consumption and a boom in tourism. The Petition describes how energy shortfalls are now exacerbated as a result of substantial facility outages caused by equipment failures.

As EPA noted in the 1993 waiver proceeding, Guam is an isolated island. 58 FR 13580. GPA generates almost all electric power used on the island (other than power generated by the United States Navy). Unlike power authorities on the mainland United States, GPA does not have the option of purchasing power from other sources. Guam is, and must remain, self sufficient with regard to energy generation.

The Petition states that Guam's energy shortfall has worsened in recent months because of facility outages caused by planned and unplanned maintenance requirements. The longstanding nature of the energy shortage has required GPA to use its existing facilities at peak capacity for several years. GPA has also deferred planned maintenance, when safety considerations have allowed, to permit units to remain in service. Because of the length of time which has elapsed since the beginning of the emergency, the result is now substantially reduced reliability of GPA's electric generating units. The Petition describes several significant and unplanned recent maintenance outages.

The construction and operation of additional, reliable baseload generating units will enable GPA to satisfy electrical demand with an appropriate margin of safety, while at the same time allowing for planned maintenance outages of generating units. Once sufficient baseload capacity exists and can be operated, routine, as well as unplanned blackouts on the island will be ended. Cabras Units Nos. 3 and 4 are such baseload units.

The Petition states that Cabras Unit No. 3 will be ready to begin operation and electrical generation on approximately August 15, 1995. The building which houses Cabras Unit No.

3 and will house Cabras Unit No. 4 has already been constructed under 40 CFR 69.11. The remaining construction of Cabras Unit No. 4 can be carried out immediately pursuant to this rulemaking.

The Petition describes a second potential difficulty with PSD permitting for the operation of Cabras Unit No. 3 and the construction of Cabras Unit No. 4. Absent changes in the current operations of the Cabras and Piti Power Plants, GPA's computer modeling suggests that the operation of the new units, combined with existing facilities, may cause exceedences of sulfur dioxide National Ambient Air Quality Standards ("NAAQS") on Orote Point, a peninsula of elevated terrain located in the offshore direction from the power plants.

GPA is re-evaluating its computer modeling results using state of the art wind tunnel modeling. Preliminary results of wind tunnel modeling seem to confirm the possibility of the exceedences projected by computer models. If a final analysis upholds that result, significant changes to power plant operations likely will be necessary in order for PSD permits to be issued for Cabras Units Nos. 3 and 4.

Section 325(a) of the CAA allows a waiver of certain CAA requirements, based upon local factors, only if the waiver will not cause exceedences of the primary NAAQS or violations of the hazardous air pollutant provisions of the CAA. The hazardous air pollutant provisions of the CAA are not affected by the Petition. The Petition is accompanied by an air quality analysis, utilizing computer modeling, which demonstrates that all NAAQS will be protected if the requested waivers are granted and incorporate the operating conditions described below.

GPA operates the Cabras and Piti Power Plants under an intermittent control strategy which utilizes fuel switching. This intermittent control strategy is described in an EPA document entitled the "Cabras Area ICS." This strategy has required the use of fuel oil with a maximum sulfur content of 1.19 percent when winds blow in an onshore direction, and the use of fuel oil with a maximum sulfur content of 2.84 percent when winds blow in an offshore direction.

As a condition of the waiver sought, GPA is to reduce the sulfur content in the fuel oil fired in the Cabras Power Plant and the Piti Power Plant when winds blow in an offshore direction. The sulfur content of the fuel used will be reduced to a maximum content of 2.00 percent. The Petition describes how GPA will obtain and assure the use

of such fuel oil prior to beginning the operation of Cabras Unit No. 3.

EPA is granting the Petition, with the conditions contained therein, and is issuing the requested waiver. Cabras Unit No. 3 will be allowed to operate prior to receipt of a PSD permit. This operation is subject to the use of fuel oil with a maximum sulfur content of 2.00 percent at the Cabras and Piti Power Plants during offshore wind conditions. Moreover, this waiver for Cabras Unit No. 3 is granted only until August 15, 1996, or until a final PSD permit is secured by GPA, whichever event occurs sooner. Cabras Unit No. 4 may be constructed, but not operated, prior to receipt of a PSD permit. Finally, a report on the results of GPA's Orote Point evaluation shall be filed with EPA by October 15, 1995.

Cabras Unit No. 3 is subject to a conditional permit to construct, issued by GEPA on May 12, 1994. GPA has filed an application to GEPA for authority to operate this unit. During the period of this waiver, GPA must comply with the requirements of these GEPA permits.

This rule is promulgated on a direct final basis. EPA is convinced that the energy emergency on Guam creates significant adverse consequences which require immediate action. As documented in the Petition, continuing planned and unplanned power outages on Guam create substantial public health and safety concerns. EPA has been furnished with descriptions of traffic intersections at which traffic lights cannot operate. The water supplies to areas on Guam are serviced by electric pumps, and EPA has also been furnished with descriptions of interruptions of water supplies due to power outages. Finally, as would be expected, significant and sustained citizen displeasure has been voiced regarding this problem. These factors constitute good cause for EPA to waive notice requirements. In this instance, a delay in the effectiveness of this waiver granted would be impracticable and contrary to the public interest. In addition, based on the lack of negative comments in the 1993 waiver proceeding, EPA believes that this is a noncontroversial rulemaking action. Therefore, EPA finds that there is good cause for a direct final rulemaking, pursuant to 5 U.S.C. 553(d)(3), and that notice and public procedures are impracticable, unnecessary, and contrary to the public interest.

GEPA has received and reviewed a copy of the Petition. It supports the issuance of this waiver.

Regulatory Analysis

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., EPA must prepare a Regulatory Flexibility Analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

This direct final rule applies only to large sources of air emissions used to generate electrical power on Guam. These sources of electrical power will be constructed, owned, and operated by GPA. This organization is not a small entity. Therefore, this rulemaking will not impact small entities.

This action has been classified as a Table 3 action for signature by the Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214-2225). The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

List of Subjects in 40 CFR Part 69

Air pollution control.

Dated: September 11, 1995.

Carol Browner,

Administrator.

Part 69 of chapter I, title 40 of the Code of Federal Regulations is amended to read as follows:

PART 69—[AMENDED]

1. The authority citation for part 69 continues to read as follows:

Authority: Section 325, Clean Air Act, as amended (42 U.S.C. 7625-1).

2. Section 69.11 is amended by adding paragraph (c) to read as follows:

§ 69.11 New exemptions.

* * * * *

(c) Pursuant to Section 325(a) of the CAA and a petition submitted by the Governor of Guam on July 14, 1995 ("1995 Petition"), the Administrator of EPA conditionally exempts Guam Power Authority ("GPA") from certain CAA requirements.

(1) A waiver of the requirement to obtain a PSD permit prior to construction is granted for the electric generating unit identified in the 1995 Petition as Cabras Unit No. 4, with the following conditions:

(i) Cabras Unit No. 4 shall not operate until a final PSD permit is received by GPA for this unit;

(ii) Cabras Unit No. 4 shall not operate until it complies with all requirements

of its PSD permit, including, if necessary, retrofitting with BACT;

(iii) If Cabras Unit No. 4 operates either prior to the issuance of a final PSD permit or without BACT equipment, Cabras Unit No. 4 shall be deemed in violation of this waiver and the CAA beginning on the date of commencement of construction of the unit.

(2) A waiver of the requirement to obtain a PSD permit prior to the operation of the unit identified in the 1995 Petition as Cabras Unit No. 3 is granted subject to the following conditions:

(i) The protocol to be followed for the ICS of fuel switching for electric generating units shall be modified to require the use of fuel oil with a sulfur content of 2.00 percent or less during offshore wind conditions. This fuel shall be fired in Cabras Power Plant Units Nos. 1 through 3 and in Piti Power Plant Units Nos. 4 and 5.

(ii) Cabras Unit No. 3 shall operate in compliance with all applicable requirements in its permits to construct and to operate as issued by Guam Environmental Protection Agency.

(iii) The waiver provisions allowing Cabras Unit No. 3 to operate prior to issuance of a PSD permit shall expire on August 15, 1996, or upon the receipt by GPA of a PSD permit for Cabras Unit No. 3, whichever event occurs first.

(3) On or before October 15, 1995, GPA shall submit to EPA, Region IX, a report concerning the operation of Cabras Unit No. 3 and the construction of Cabras Unit No. 4. The report shall contain:

(i) A summary of GPA's conclusions from its wind tunnel study;

(ii) A description of the alternatives available to assure compliance with all air quality requirements, including PSD requirements, during the operation of Cabras Units Nos. 3 and 4;

(iii) A description of the alternative GPA chooses to assure compliance with all air quality requirements, including PSD requirements, during the operation of Cabras Units Nos. 3 and 4; and

(iv) A plan of implementation by GPA.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 405

[BPD-766-F]

RIN 0938-AG21

Medicare Program; Standards for Quality of Water Used in Dialysis and Revised Guidelines on Reuse of Hemodialysis Filters for End-Stage Renal Disease (ESRD) Patients

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Medicare conditions for coverage of suppliers of end-stage renal disease services. The revisions remove general language in the regulations regarding water quality; incorporate by reference standards for monitoring the quality of water used in dialysis as published by the Association for the Advancement of Medical Instrumentation (AAMI) in its document, "Hemodialysis Systems" (second edition); and update existing regulations to incorporate by reference the second edition of AAMI's voluntary guidelines on "Reuse of Hemodialyzers."

EFFECTIVE DATE: These regulations are effective on October 18, 1995. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 18, 1995.

FOR FURTHER INFORMATION CONTACT: Jackie Sheridan, (410) 966-4635.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1881 of the Social Security Act (the Act) authorizes Medicare coverage and payment for the treatment of end-stage renal disease (ESRD) in approved facilities that provide dialysis to ESRD patients. The Health Care Financing Administration (HCFA) grants approval of ESRD facilities after they have been surveyed by a State agency. The State survey agency determines the facility's compliance with the conditions specified in regulations at 42 CFR part 405, subpart U. Medicare payment is limited to ESRD services furnished by facilities meeting these conditions.

A. Water Quality

The existing regulation governing the quality of water used in dialysis (§ 405.2140(a)(5)) requires that the water be analyzed periodically and treated as

necessary to maintain a continuous supply that is biologically and chemically compatible with acceptable dialysis techniques. The lack of specificity of these requirements makes it difficult for State agency surveyors to measure facility compliance with the standard.

Realizing that water quality is one of the most important aspects of health and safety in dialysis led us to consult with the Public Health Service and various other professionals in the dialysis industry to redefine the standards used by State surveyors in determining compliance with the regulations. As a result of these consultations, we concluded that there was a need to establish specific measurable standards regarding the quality of water used in dialysis. According to the Public Health Service's Center for Disease Control and Prevention, the Association for the Advancement of Medical Instrumentation (AAMI) standard on water quality is the only standard available, is accepted by the medical community and is currently used by most facilities.

The 1992 AAMI standard, "Hemodialysis Systems," reflects the collective expertise of a committee of health care professionals, in conjunction with device manufacturers and government representatives. This committee developed a standard of performance for manufacturers that will, at a minimum, promote the effective, safe performance of hemodialysis systems, devices, and related materials. The standard includes specific water quality requirements and has an appendix that provides a guideline for the device user with specific emphasis on water purity assurance and monitoring. This standard is outcome-oriented in that it stipulates only specific biological and chemical water purity levels and does not restrict the methods used by facilities to attain and maintain the acceptable levels.

Each AAMI standard or recommended practice is reviewed at least every 5 years because of constant changes in medical technology and to clarify or improve existing guidelines. The standard was originally published in 1982. In 1986, the AAMI Renal Disease and Detoxification Committee appointed task groups to carefully review specific areas of the standard. After review by the task groups and the full committee, a proposed revision was drafted. This document, "Hemodialysis Systems" (second edition), was voted on by the committee, reviewed by the public, and was approved on March 16, 1992.