

**List of Subjects in 21 CFR Part 314**

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 314 be amended as follows:

**PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG**

1. The authority citation for 21 CFR part 314 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e).

2. Section 314.420 is amended by removing and reserving paragraph (a)(1), and by revising the second sentence of paragraph (a)(5) to read as follows:

**§ 314.420 Drug master files.**

(a) \* \* \*

(1) [Reserved]

\* \* \* \* \*

(5) \* \* \* (A person wishing to submit information and supporting data in a drug master file (DMF) that is not covered by Types II through IV DMF's must first submit a letter of intent to the Drug Master File Staff, Food and Drug Administration, 12420 Parklawn Dr., rm. 2-14, Rockville, MD 20857. \* \* \*)

\* \* \* \* \*

Dated: June 26, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95-16206 Filed 6-30-95; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF THE INTERIOR****Bureau of Indian Affairs****25 CFR Chapter I****Meeting of the Indian Self-Determination Negotiated Rulemaking Committee**

**AGENCY:** Bureau of Indian Affairs, Interior Indian Health Service, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Secretary of the Interior (DOI) and the Secretary of Health and Human Services (DHHS) have established an Indian Self-Determination Negotiated Rulemaking Committee (Committee) to negotiate and develop a proposed rule implementing the Indian Self-Determination and

Education Assistance Act (ISDEAA), as amended.

The Departments have determined that the establishment of this Committee is in the public interest and will assist the agencies in developing regulations authorized under section 107 of the ISDEAA. The agenda for this meeting will consist of workgroup reports on the advantages and disadvantages of developing regulations in those subject areas provided in ISDEAA where regulations are permitted. In addition, further meeting and work assignments will be planned.

**DATES:** The Committee and appropriate workgroups will meet on the following days beginning at approximately 8:30 am and ending at approximately 5:00 pm on each day: Sunday, July 9, Monday, July 10, Tuesday, July 10, Wednesday, July 12, Thursday, July 13.

**ADDRESSES:** All meetings July 9 through July 13, 1995, will be held at the Red Lion Hotel, 3203 Quebec Street, Denver, CO 80207. Tel.: (303) 321-3333. (Workgroups will also be meeting at the same location.)

It was originally planned that this meeting be held in Oklahoma City, however, organizers were unable to find adequate accommodations in Oklahoma City or Tulsa. Due to the lack of space at these preferred locations, the site for the meeting has been changed to Denver Colorado. Also the difficulty of confirming a meeting location in Oklahoma has made it necessary that this notice be published within the prescribed 15 days of the actual beginning of the meeting. Committee activities begin on Sunday, July 9, and will continue through Thursday, July 13. Activities will include meetings of the full committee as well as various workgroup sessions.

Written statements may be submitted to Mr. James J. Thomas, Chief, Division of Self-Determination Services, Bureau of Indian Affairs, 1849 C Street, NW, MS: 4627-MIB, Washington, DC 20240, telephone (202) 208-3708.

**FOR FURTHER INFORMATION CONTACT:** Mr. James J. Thomas, Chief, Division of Self-Determination Services, Bureau of Indian Affairs, 1849 C Street, NW., MS: 4627-MIB, Washington, DC 20240, telephone (202) 208-3708; or Mrs. Merry Elrod, Acting Director, Division of Self-Determination, Indian Health Service, 5600 Fishers Lane, Parklawn Building, Room 6A-05, Rockville, MD 20857, telephone (301) 443-1044.

**SUPPLEMENTARY INFORMATION:** The location and dates of future meetings will be published in the **Federal Register**. The meetings will be open to

the public without advanced registration.

Public attendance may be limited to the space available. Members of the public may make statements during the meeting, to the extent time permits and file written statements with the Committee for its consideration. Written statements should be submitted to the address listed above. Summaries of Committee meetings will be available for public inspection and copying ten days following each meeting at the same address. In addition, the materials received to date during the input sessions are available for inspection and copying at the same address.

Dated: June 28, 1995.

**Ada E. Deer,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 95-16351 Filed 6-30-95; 8:45 am]

BILLING CODE 4310-02-M

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Parts 52 and 70**

[CA 147-2-7073; AD-FRL-5253-2]

**Clean Air Act Proposed Interim Approval of the Operating Permits Program; Proposed Approval of State Implementation Plan Revision for the Issuance of Federally Enforceable State Operating Permits; Mojave Desert Air Quality Management District, California**

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

**ACTION:** Proposed rule.

**SUMMARY:** The EPA proposes interim approval of the title V operating permits program submitted by the Mojave Desert Air Quality Management District (Mojave Desert, or District) for the purpose of complying with federal requirements that mandate that states develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources. There are nine deficiencies in Mojave Desert's program, as specified in the Technical Support Document and outlined below, that must be corrected before the program can be fully approved. EPA is also proposing to approve a revision to Mojave Desert's portion of the California State Implementation Plan (SIP) regarding synthetic minor regulations for the issuance of federally enforceable state operating permits (FESOP). In order to extend the federal enforceability of state operating permits to hazardous air pollutants (HAP), EPA

is also proposing approval of Mojave Desert's synthetic minor regulations pursuant to section 112 of the Act. Today's action also proposes approval of Mojave Desert's mechanism for receiving straight delegation of section 112 standards.

**DATES:** Comments on these proposed actions must be received in writing by August 2, 1995.

**ADDRESSES:** Comments should be addressed to Sara Bartholomew, Mail Code A-5-2, U.S. Environmental Protection Agency, Region IX, Air & Toxics Division, 75 Hawthorne Street, San Francisco, CA 94105.

Copies of the District's submittal and other supporting information used in developing the proposed interim approval are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

**FOR FURTHER INFORMATION CONTACT:** Sara Bartholomew (telephone 415/744-1170), Mail Code A-5-2, U.S. Environmental Protection Agency, Region IX, Air & Toxics Division, 75 Hawthorne Street, San Francisco, CA 94105.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background and Purpose**

As required under title V of the Clean Air Act (Act) as amended (1990), EPA has promulgated rules that define the minimum elements of an approvable state operating permits program and the corresponding standards and procedures by which the EPA will approve, oversee, and withdraw approval of state operating permits programs (see 57 FR 32250 (July 21, 1992)). These rules are codified at 40 CFR part 70 (part 70). Title V requires states to develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources.

The Act requires that states develop and submit title V programs to EPA by November 15, 1993, and that EPA act to approve or disapprove each program within 1 year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the Act and the part 70 regulations, which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of part 70, EPA may grant the program interim approval for a period of up to 2 years. If EPA has not fully approved a program by 2 years after the November 15, 1993 date, or by the end of an interim program, it must

establish and implement a federal program.

On June 28, 1989 (54 FR 27274), EPA published criteria for approving and incorporating into the SIP regulatory programs for the issuance of federally enforceable state operating permits. Permits issued pursuant to an operating permit program meeting these criteria and approved into the SIP are considered federally enforceable. EPA has encouraged states to consider developing such programs in conjunction with title V operating permit programs for the purpose of creating federally enforceable limits on a source's potential to emit. This mechanism would enable sources to reduce their potential to emit to below the title V applicability thresholds and avoid being subject to title V. (See the guidance document entitled, "Limitation of Potential to Emit with Respect to Title V Applicability Thresholds," dated September 18, 1992, from John Calcagni, Director of EPA's Air Quality Management Division.) On November 3, 1993, EPA announced in a guidance document entitled, "Approaches to Creating Federally Enforceable Emissions Limits," signed by John S. Seitz, Director of EPA's Office of Air Quality Planning and Standards (OAQPS), that this mechanism could be extended to create federally enforceable limits for emissions of hazardous air pollutants (HAP) if the program were approved pursuant to section 112(l) of the Act.

##### **II. Proposed Action and Implications**

This document focuses on specific elements of Mojave Desert's title V operating permits program submittal that must be corrected to meet the minimum requirements of 40 CFR part 70. The full program submittal, the Technical Support Document containing a detailed analysis of the full program, and other relevant materials are available as part of the public docket.

###### *A. Analysis of State Submission*

###### **1. Title V Support Materials**

Mojave Desert's title V program was submitted by the California Air Resources Board (CARB) on November 24, 1993 and found by EPA to be incomplete, due to the lack of Federal Operating Permit regulations. Mojave resubmitted its program on March 10, 1995 and it was found to be complete on May 11, 1995. The Governor's letter requesting source category-limited interim approval, California enabling legislation, and Attorney General's legal opinion were submitted by CARB for all

districts in California and therefore were not included separately in Mojave Desert's submittal. The Mojave Desert submission does contain a complete program description, District implementing and supporting regulations, and all other program documentation required by § 70.4. An implementation agreement between Mojave Desert and EPA is currently being developed.

###### **2. Title V Operating Permit Regulations and Program Implementation**

The Mojave Desert's title V regulations were adopted on December 21, 1994. They consist of Regulation XII (Federal Operating Permits). The District also submitted supporting materials including the following rules: Rule 219 (Equipment Not Requiring a Permit, adopted December 21, 1994), 221 (Federal Operating Permit Requirement, adopted November 23, 1994), 301 (Permit Fees, adopted July 9, 1976, amended October 23, 1994), 312 (Fees for Federal Operating Permits, adopted December 21, 1994), and 430 (Breakdown Provisions, adopted May 7, 1976, amended December 21, 1994). These regulations "substantially meet" the requirements of 40 CFR part 70, § 70.2 and § 70.3 for applicability; § 70.4, § 70.5, and § 70.6 for permit content, including operational flexibility; § 70.7 for public participation and minor permit modifications; § 70.5 for complete application forms; and § 70.11 for enforcement authority. Although the regulations substantially meet part 70 requirements, nine program deficiencies outlined below are interim approval issues. Recommended changes are detailed further in the Technical Support Document.

*Variances*—Mojave Desert has authority under State and local law to issue a variance from State and local requirements. Sections 42350 *et seq.* of the California Health and Safety Code and District Regulation 1, sections 431-433 allow the District to grant relief from enforcement action for permit violations. The EPA regards these provisions as wholly external to the program submitted for approval under part 70, and consequently, is proposing to take no action on these provisions of State and local law.

The EPA has no authority to approve provisions of state or local law, such as the variance provisions referred to, that are inconsistent with the Act. The EPA does not recognize the ability of a permitting authority to grant relief from the duty to comply with a federally enforceable part 70 permit, except where such relief is granted through

procedures allowed by part 70. A part 70 permit may be issued or revised (consistent with part 70 permitting procedures) to incorporate those terms of a variance that are consistent with applicable requirements. A part 70 permit may also incorporate, via part 70 permit issuance or modification procedures, the schedule of compliance set forth in a variance. However, EPA reserves the right to pursue enforcement of applicable requirements notwithstanding the existence of a compliance schedule in a permit to operate. This is consistent with 40 CFR 70.5(c)(8)(iii)(C), which states that a schedule of compliance "shall be supplemental to, and shall not sanction noncompliance with, the applicable requirements on which it is based."

**Insignificant Activities**—Section 70.4(b)(2) requires states to include in their part 70 programs any criteria used to determine insignificant activities or emission levels for the purpose of determining complete applications. Section 70.5(c) states that an application for a part 70 permit may not omit information needed to determine the applicability of, or to impose, any applicable requirement, or to evaluate appropriate fee amounts. Section 70.5(c) also states that EPA may approve, as part of a state program, a list of insignificant activities and emissions levels which need not be included in permit applications. Under part 70, a state must request and EPA must approve as part of that state's program any activity or emission level that the state wishes to consider insignificant. Part 70, however, does not establish appropriate emission levels for insignificant activities, relying instead on a case-by-case determination of appropriate levels based on the particular circumstances of the part 70 program under review.

In Rule 219 (Equipment Not Requiring a Permit) Mojave Desert provided both threshold emissions levels and a list of specific equipment which would not require a permit. This rule also clearly states that equipment need not be listed in a permit application for a federal operating permit if it falls below the threshold, is on the list of equipment in the rule, is not subject to an applicable requirement, and is not included in the equipment list solely due to size or production rate. The only weakness in these gatekeepers is that the word "and" is missing between sections (B)(1)(b) and (c), and (B)(1)(c) and (d) of Rule 219. Adding "and" in these two places would clarify that all of the four gatekeepers must apply for equipment to be exempt, not just one. These

corrections must be made in order to receive full approval.

Rule 219 set the threshold criteria for equipment to be exempt from a federal operating permit as 10% of the applicable threshold for determination of a major source, or 5 tons per year of any regulated air pollutant (whichever is less), and for HAP any de minimis level, any significance level, or 0.5 tons per year (whichever is less). For other state and district programs, EPA has proposed to accept, as sufficient for full approval, emission levels for insignificant activities of 2 tons per year for criteria pollutants and the lesser of 1000 pounds per year, section 112(g) de minimis levels, or other title I significant modification levels for HAP and other toxics (40 CFR 52.21(b)(23)(i)). EPA believes that these levels are sufficiently below the applicability thresholds of many applicable requirements to assure that no unit potentially subject to an applicable requirement is left off a title V application.

Mojave Desert did not describe the criteria used to determine the insignificant activities or emission levels outlined in Rule 219. In addition, Mojave's threshold levels as described above are higher than those EPA has proposed to accept. Because of this, EPA is requesting comment on the appropriateness of these emission levels for determining insignificant activities in Mojave Desert. This request for comment is not intended to restrict the ability of other states and districts to propose, and EPA to approve, different emission levels if the state or district demonstrates that such alternative emission levels are insignificant compared to the level of emissions from and types of units that are permitted or subject to applicable requirements.

### 3. Title V Permit Fee Demonstration

Section 502(b)(3) of the Act requires that each permitting authority collect fees sufficient to cover all reasonable direct and indirect costs required to develop and administer its title V operating permits program. Each title V program submittal must contain either a detailed demonstration of fee adequacy or a demonstration that aggregate fees collected from title V sources meet or exceed \$25 per ton of emissions per year (adjusted from 1989 by the Consumer Price Index (CPI)). The \$25 per ton amount is presumed, for program approval, to be sufficient to cover all reasonable program costs and is thus referred to as the "presumptive minimum." See § 70.9(b)(2)(i).

Mojave Desert has opted to make a presumptive minimum fee

demonstration. Mojave Desert's existing fee schedule (Element 7) requires title V facilities to pay an amount equivalent to \$48.76 per ton in annual operating fees. This amount meets EPA's presumptive minimum (CPI adjusted). The \$48.76 per ton amount is based on a calculation of 1993/94 fee revenues per ton of emissions plus a supplemental title V fee of 14.3% that covers the additional costs posed by title V. Mojave Desert will maintain an accounting system and is prepared to increase fees, as needed, to reflect actual program implementation costs.

### 4. Provisions Implementing the Requirements of Other Titles of the Act

a. Section 112—Mojave Desert has demonstrated in its title V program submittal adequate legal authority to implement and enforce all section 112 requirements through the title V permit. This legal authority is contained in the State of California enabling legislation and in regulatory provisions defining "applicable requirements" and "federally enforceable" and mandating that all federal air quality requirements must be incorporated into permits. EPA has determined that this legal authority is sufficient to allow Mojave Desert to issue permits that assure compliance with all section 112 requirements. For further discussion, please refer to the Technical Support Document accompanying this action and the April 13, 1993 guidance memorandum entitled, "Title V Program Approval Criteria for Section 112 Activities," signed by John Seitz.

b. Title IV—Mojave Desert is submitting proposed Rule 1210 (Acid Rain Provisions of Federal Operating Permits) to its Board in June, 1995, which incorporates the pertinent provisions of part 72, either by reference or in specific language in the rule. EPA interprets "pertinent provisions" to include all provisions necessary for the permitting of affected sources.

### B. Proposal for and Implications of Interim Approval

#### 1. Title V Operating Permits Program

a. *Proposed Interim Approval*—The EPA is proposing to grant interim approval to the operating permits program submitted by CARB on behalf of Mojave Desert on March 10, 1995. Following interim approval, Mojave Desert must make the following changes to receive full approval:

(1) Revise Rule 1203(G)(3)(g), which prohibits the permit shield from applying to Administrative Permit Amendments and Significant Permit Modifications, to include a reference to

Minor Permit Modifications as well. The permit shield cannot apply to Minor Permit Modifications, and the rule must state this clearly. See § 70.7(e)(2)(vi).

(2) Add a provision for sending the final permit to EPA, as required by § 70.8(a)(1). Mojave's Rule 1203(B)(1)(c) only provides for sending the proposed permit to EPA.

(3) Adopt Rule 1210 (Acid Rain Provisions of Federal Operating Permits).

(4) Rule 1206(A)(1)(i) must amend the provision that no reopening is required if the effective date of the additional applicable requirement is later than the date on which the permit is due to expire. If the original permit or any of its terms and conditions are extended pursuant to § 70.4(b)(10), the permit *must* be reopened to include a new applicable requirement, and a statement must be made to this effect in Mojave's rule (§ 70.7(f)(1)(i)).

(5) Clarify in Rule 1203(G)(3)(B) that the permit shield shall not limit liability for violations which occurred prior to *or at* the time of the issuance of the federal operating permit, by adding the underlined words. This is important to clarify that violations which are continuing at the time of permit issuance will not be shielded against.

(6) Lower the cutoff levels for criteria pollutants in Rule 219 (Equipment not Requiring a Permit) or, alternatively, demonstrate that Mojave Desert's levels are insignificant compared to the level of emissions from and types of units that are required to be permitted or are subject to applicable requirements.

(7) Add "and" at the end of sections (b) and (c) in Rule 219(B)(2), in order to clarify that the four gatekeepers must all apply in order for equipment to be exempt from getting a federal operating permit.

(8) Add to Rule 1203(D)(1)(e)(i) a reference to the requirement for the clear identification of all deviations with respect to reporting (§ 70.6(a)(3)(iii)(A)).

(9) Add to Rule 1203(D)(1)(e)(ii) a reference to the requirement to specify the probable cause and corrective actions or preventive measures taken with regard to reporting a deviation (§ 70.6(a)(3)(iii)(B)).

*b. Legislative Source Category-Limited Interim Approval Issue*—In addition to the District-specific issues arising from Mojave Desert's program submittal and locally adopted regulations, California State law currently exempts agricultural production sources from permit requirements. Because of this exemption, California programs are only eligible for source category-limited interim approval. In order for this

program to receive full approval (and avoid a disapproval upon the expiration of this interim approval), the California Legislature must revise the Health and Safety Code to eliminate the exemption of agricultural production sources from the requirement to obtain a permit.

*c. Implications of Interim Approval*—The above described program and legislative deficiencies must be corrected before Mojave Desert can receive full program approval. For additional information, please refer to the Technical Support Document, which contains a detailed analysis of Mojave Desert's operating permits program, and California's enabling legislation.

Interim approval, which may not be renewed, would extend for a period of 2 years. During the interim approval period, the District would be protected from sanctions, and EPA would not be obligated to promulgate a federal permits program in the Mojave Desert. Permits issued under a program with interim approval would have full standing with respect to part 70, and the 1-year time period for submittal of permit applications by subject sources would begin upon EPA's final rulemaking granting interim approval, as would the 3-year time period for processing initial permit applications.

Following final interim approval, if Mojave Desert should fail to submit a complete corrective program for full approval by the date 6 months before expiration of the interim approval, EPA would start an 18-month clock for mandatory sanctions. Then, if Mojave Desert should fail to submit a corrective program that EPA found complete before the expiration of that 18-month period, EPA would be required to apply one of the sanctions in section 179(b) of the Act, which would remain in effect until EPA determined that the District corrected the deficiency by submitting a complete corrective program. If, six months after application of the first sanction, the Mojave Desert still had not submitted a corrective program that EPA found complete, a second sanction would be required.

If, following final interim approval, EPA were to disapprove Mojave Desert's complete corrective program, EPA would be required to apply one of the section 179(b) sanctions on the date 18 months after the effective date of the disapproval unless prior to that date the District submitted a revised program and EPA determined that it corrected the deficiencies that prompted the disapproval. Again, if, six months after EPA applied the first sanction, Mojave Desert had not submitted a revised program that EPA determined corrected

the deficiencies, a second sanction would be required. In addition, discretionary sanctions may be applied where warranted any time after the end of an interim approval period if a state or district has not submitted a timely and complete corrective program or EPA has disapproved a submitted corrective program. Moreover, if EPA has not granted full approval to a state or district program by the expiration of an interim approval and that expiration occurs after November 15, 1995, EPA must promulgate, administer and enforce a federal permits program for that state or district upon interim approval expiration.

## 2. Section 112(g) Implementation

EPA has decided that it is not reasonable to expect the states and districts to implement section 112(g) before a rule is issued. EPA therefore published an interpretive notice in the **Federal Register** regarding section 112(g) of the Act: 60 FR 8333 (February 14, 1995). This notice outlines EPA's revised interpretation of 112(g) applicability prior to EPA's issuing the final 112(g) rule. The notice states that major source modifications, constructions, and reconstructions will not be subject to 112(g) requirements until the final rule is promulgated. EPA expects to issue the 112(g) final rule in September 1995.

The notice further explains that EPA is considering whether the effective date of section 112(g) should be delayed beyond the date of promulgation of the Federal rule so as to allow States and Districts time to adopt rules implementing the Federal rule, and that EPA will provide for any such additional delay in the final section 112(g) rulemaking. Unless and until EPA provides for such an additional postponement of section 112(g), Mojave Desert must be able to implement section 112(g) during the period between promulgation of the Federal section 112(g) rule and adoption of implementing District regulations.

For this reason, EPA is proposing to approve the use of Mojave Desert's preconstruction review programs as a mechanism to implement section 112(g) during the transition period between promulgation of the section 112(g) rule and adoption by the nineteen districts of rules specifically designed to implement section 112(g). However, since approval is intended solely to confirm that Mojave Desert has a mechanism to implement section 112(g) during the transition period, the approval itself will be without effect if EPA decides in the final section 112(g) rule that there will be no transition period. The EPA is

limiting the duration of its approval of the use of preconstruction programs to implement 112(g) to 12 months following promulgation by EPA of the section 112(g) rule.

### 3. Program for Delegation of Section 112 Standards as Promulgated

Requirements for part 70 program approval, specified in 40 CFR 70.4(b), encompass section 112(l)(5) requirements for approval of a program for delegation of section 112 standards as promulgated by EPA as they apply to part 70 sources. Section 112(l)(5) requires that the District's program contain adequate authorities, adequate resources for implementation, and an expeditious compliance schedule, which are also requirements under part 70. Therefore, the EPA is also proposing to grant approval under section 112(l)(5) and 40 CFR 63.91 of Mojave Desert's program for receiving delegation of section 112 standards that are unchanged from the federal standards as promulgated. California Health and Safety Code section 39658 provides for automatic adoption by CARB of section 112 standards upon promulgation by EPA. Section 39666 of the Health and Safety Code requires that districts then implement and enforce these standards. Thus, when section 112 standards are automatically adopted pursuant to section 39658, Mojave Desert will have the authority necessary to accept delegation of these standards without further regulatory action by the District. The details of this mechanism and the means for finalizing delegation of standards will be set forth in a Memorandum of Agreement between Mojave Desert and EPA, expected to be completed prior to approval of Mojave Desert's section 112(l) program for straight delegations. This program applies to both existing and future standards but is limited to sources covered by the part 70 program.

### 4. State Operating Permit Program for Synthetic Minors

On March 31, 1995, CARB submitted for approval into the Mojave Desert's portion of the California State Implementation Plan (SIP) a local operating permit program designed to create federally enforceable limits on a source's potential to emit. This District program is referred to as a synthetic minor operating permit program, and it consists of regulations that will be integrated with the District's existing, non-federally enforceable, operating permit program. Such programs are also referred to as federally enforceable state operating permit (FESOP) programs. This synthetic minor or FESOP

mechanism will allow sources to reduce their potential to emit to below the title V applicability thresholds and avoid being subject to title V.

Mojave Desert's synthetic minor regulations were adopted on November 23, 1994 and codified in District Regulation XII, Rule 221 (Federal Operating Permit Requirement). EPA found the initial SIP submittal complete on May 25, 1995.

The five criteria for approving a state operating permit program into a SIP were set forth in the June 28, 1989 **Federal Register** notice (54 FR 27282): (1) The program must be submitted to and approved by EPA; (2) the program must impose a legal obligation on the operating permit holders to comply with the terms and conditions of the permit, and permits that do not conform with the June 28, 1989 criteria shall be deemed not federally enforceable; (3) the program must contain terms and conditions that are at least as stringent as any requirements contained in the SIP or enforceable under the SIP or any other section 112 or other Clean Air Act standard or requirement; (4) permits issued under the program must contain conditions that are permanent, quantifiable, and enforceable as a practical matter; and (5) permits issued under the program must be subject to public participation.

Permits issued under an approved program are federally enforceable and may be used to limit the potential to emit of sources of criteria pollutants. Mojave Desert's synthetic minor provisions of Regulation XII, Rule 221 meet the June 28, 1989 criteria by ensuring that the limits will be permanent, quantifiable, and practically enforceable and by providing adequate notice and comment to EPA and the public. Please refer to the Technical Support Document for a thorough analysis of the June 28, 1989 criteria as applied to the Mojave Desert's synthetic minor program.

EPA is proposing to approve pursuant to part 52 and the approval criteria specified in the June 28, 1989 **Federal Register** notice the following regulation that was submitted to create the synthetic minor operating permit program: Rule 221 (Federal Operating Permit Requirement).

On March 10, 1995, in its title V program submittal under "Addendum: Federal Clean Air Act Section 112(l) Authority Request Letter," CARB requested approval of Mojave Desert's synthetic minor program, consisting of the rules specified above, under section 112(l) of the Act for the purpose of creating federally enforceable limitations on the potential to emit of

hazardous air pollutants (HAP). The separate request for approval under section 112(l) is necessary because the proposed SIP approval discussed above only provides a mechanism for controlling criteria pollutants. While federally enforceable limits on criteria pollutants (i.e., VOC's or PM-10) may have the incidental effect of limiting certain HAP listed pursuant to section 112(b)<sup>1</sup>, section 112 of the Act provides the underlying authority for controlling HAP emissions that are not criteria pollutants. As a legal matter, no additional program approval by EPA is required in order for these criteria pollutant limits to be recognized as federally enforceable.

EPA has determined that the five approval criteria for approving FESOP programs into the SIP, as specified in the June 28, 1989 **Federal Register** notice, are also appropriate for evaluating and approving the programs under section 112(l). The June 28, 1989 notice does not address HAP because it was written prior to the 1990 amendments to section 112 (which injected the concept of major HAP sources versus non-major or area HAP sources into the permit) and not because it establishes requirements unique to criteria pollutants. Hence, the five criteria outlined above are applicable to FESOP approvals under section 112(l).

In addition to meeting the criteria in the June 28, 1989 notice, a FESOP program that will control HAP emissions must meet the statutory criteria for approval under section 112(l)(5). Section 112(l)(5) allows EPA to approve a program only if it: (1) Contains adequate authority to assure compliance with any section 112 standard or requirement; (2) provides for adequate resources; (3) provides for an expeditious schedule for assuring compliance with section 112 requirements; and (4) is otherwise likely to satisfy the objectives of the Act.

The EPA plans to codify the approval criteria for programs limiting potential to emit of HAP in subpart E of part 63 (Subpart E), the regulations promulgated to implement section 112(l) of the Act. The EPA currently anticipates that these criteria, as they apply to FESOP programs controlling HAP, will mirror those set forth in the June 28, 1989 notice, with the addition that the state's authority must extend to all HAP, instead of, or in addition to, VOC's and PM-10. The EPA currently anticipates that FESOP programs that are approved

<sup>1</sup> The EPA intends to issue guidance addressing the technical aspects of how these criteria pollutant limits may be recognized for purposes of limiting a source's potential to emit of HAP to below section 112 major source levels.

pursuant to section 112(l) prior to the Subpart E revisions will have had to meet these criteria, and hence, will not be subject to any further approval action.

The EPA believes it has authority under section 112(l) to approve programs to limit potential to emit of HAP directly under section 112(l) prior to this revision to Subpart E. Section 112(l)(5) requires EPA to disapprove programs that are inconsistent with guidance required to be issued under section 112(l)(2). This might be read to suggest that the "guidance" referred to in section 112(l)(2) was intended to be a binding rule. Even under this interpretation, the EPA does not believe that section 112(l) requires this rulemaking to be comprehensive. That is, it need not address all instances of approval under section 112(l). Given the severe timing problems posed by impending deadlines set forth in MACT standards and for submittal of title V applications, EPA believes it is reasonable to read section 112(l) to allow for approval of programs to limit potential to emit prior to issuance of a rule specifically addressing this issue.

EPA proposes approval of Mojave Desert's synthetic minor program pursuant to section 112(l) because the program meets all of the approval criteria specified in the June 28, 1989 **Federal Register** notice and in section 112(l)(5) of the Act. Please refer to the Technical Support Document for a complete discussion of how the June 28, 1989 criteria are met by the Mojave Desert. Regarding the statutory criteria of section 112(l)(5) referred to above, the EPA believes Mojave Desert's synthetic minor program contains adequate authority to assure compliance with section 112 requirements since the third criterion of the June 28, 1989 notice is met: the program does not provide for waiving any section 112 requirement. Sources would still be required to meet section 112 requirements applicable to non-major sources. Furthermore, EPA believes that Mojave Desert's synthetic minor program provides for an expeditious schedule for assuring compliance because it allows a source to establish a voluntary limit on potential to emit and avoid being subject to a federal Clean Air Act requirement applicable on a particular date. Nothing in Mojave Desert's program would allow a source to avoid or delay compliance with a federal requirement if it fails to obtain the appropriate federally enforceable limit by the relevant deadline. Finally, Mojave Desert's synthetic minor program is consistent with the objectives of the section 112 program because its purpose is to enable

sources to obtain federally enforceable limits on potential to emit to avoid major source classification under section 112. The EPA believes this purpose is consistent with the overall intent of section 112, which is to decrease the amount of HAP being emitted; by committing to stay below a certain emission level for HAP, a source with a synthetic minor permit is achieving this goal.

### III. Administrative Requirements

#### A. Request for Public Comments

The EPA is requesting comments on all aspects of this proposed interim approval. Copies of Mojave Desert's submittal and other information relied upon for the proposed interim approval are contained in a docket maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this proposed interim approval. The principal purposes of the docket are:

(1) To allow interested parties a means to identify and locate documents so that they can effectively participate in the approval process, and

(2) To serve as the record in case of judicial review. The EPA will consider any comments received by August 2, 1995.

#### B. Executive Order 12866

The Office of Management and Budget has exempted this action from Executive Order 12866 review.

#### C. Regulatory Flexibility Act

The EPA's actions under sections 502, 110, and 112 of the Act do not create any new requirements, but simply address operating permit programs submitted to satisfy the requirements of 40 CFR part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

#### Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for

informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed approval action promulgated today does not include a federal mandate that may result in estimated costs of \$100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This proposed federal action approves pre-existing requirements under state or local law, and imposes no new federal requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

#### List of Subjects 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides, Volatile organic compounds.

#### 40 CFR Part 70

Administrative practice and procedure, Air pollution control, Environmental protection, Hazardous substances, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

**Authority:** 42 U.S.C. 7401-7671q.

Dated: June 23, 1995.

**David P. Howekamp,**

*Acting Regional Administrator.*

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#### 40 CFR Part 70

[KS-001; AD-FRL-5252-2]

#### Clean Air Act Proposed Full Approval of Operating Permits Program; State of Kansas, and Delegation of 112(l) Authority

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

**ACTION:** Proposed full approval.

**SUMMARY:** The EPA proposes full approval of the Operating Permits Program submitted by the state of Kansas, for the purpose of complying with Federal requirements for states which develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources. This notice explains EPA's rationale for the proposed action, and identifies several revisions to the program which must be made before EPA can take final action to approve it.