

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the direct final rule and this companion proposed rule will be considered under this proposed rule.

#### List of Subjects in 21 CFR Part 2

Administrative practice and procedure, Cosmetics, Drugs, Foods.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 2 is proposed to be amended as follows:

#### PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. The authority citation for 21 CFR part 2 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 335, 342, 346a, 348, 351, 352, 355, 357, 360b, 361, 371, 372, 374; 15 U.S.C. 402, 409.

2. Section 2.10 is amended by revising paragraph (b)(2) to read as follows:

#### § 2.10 Examination and investigation samples.

\* \* \* \* \*

(b) \* \* \*

(2) The cost of twice the quantity so estimated exceeds \$150.

\* \* \* \* \*

Dated: September 11, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-25359 Filed 9-24-98; 8:45 am]

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#### DEPARTMENT OF THE INTERIOR

#### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 938

[PA-122-FOR]

#### Pennsylvania Regulatory Program

**AGENCY:** OSM, Interior.

**ACTION:** Proposed rule; notice of hearing and extension of comment period.

**SUMMARY:** In a letter dated July 29, 1998 (Administrative Record No. PA-841.07), the Pennsylvania Department of Environmental Protection submitted to OSM proposed regulatory amendments to the Pennsylvania regulatory program

under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment proposes changes to the Pennsylvania program with regard to the mine subsidence control, subsidence damage repair or replacement, and water supply replacement provisions of SMCRA. The amendment submission included Act 54 and implementing regulations. OSM announced receipt of the amendment in the August 25, 1998, **Federal Register** (63 FR 45199) and solicited public comments on the proposed regulatory changes. The August 25, 1998, notice stated that the public comment period would end on September 24, 1998, and if a hearing on the amendment is requested, that the hearing would be held on September 21, 1998.

Several individuals requested that a public hearing be held in Washington, Pennsylvania. These individuals also requested additional time to prepare for the hearing. OSM is honoring this request in order to give interested parties ample notification of the hearing location, and ample time to prepare their comments for the hearing. As a result, the deadline for submitting public comments has been extended.

This notice sets forth the times and location of the pending public hearing, and the extended deadline that public comments can be submitted to OSM regarding the adequacy of the proposed amendment.

**DATES:** Written comments must be received on or before 4:00 p.m. on October 19, 1998, to ensure consideration in the rulemaking process. The public hearing will be held at 6:30 p.m. on October 13, 1998.

**ADDRESSES:** Written comments and requests to testify at the hearing should be mailed or hand-delivered to Mr. Robert J. Biggi, Director, Harrisburg Field Office at the first address listed below.

Copies of the Pennsylvania program, the proposed amendment, a listing of any scheduled public meetings or hearing, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays:

Office of Surface Mining Reclamation and Enforcement, Harrisburg Field Office, Third Floor, Suite 3C, Harrisburg Transportation Center, 415 Market Street, Harrisburg, Pennsylvania 17101, Telephone: (717) 782-4036.

Pennsylvania Department of Environmental Protection, Bureau of Mining and Reclamation, Rachel Carson State Office Building, P.O. Box 8461,

Harrisburg, Pennsylvania 17105-8461, Telephone: (717) 787-5103.

Each requester may receive, free of charge, one copy of the proposed amendment by contacting the OSM Harrisburg Field Office.

The public hearing will be held at the Ramada Inn, 1170 West Chestnut Street, Washington, Pennsylvania 15301-4631.

**FOR FURTHER INFORMATION CONTACT:** Robert J. Biggi, Director, Harrisburg Field Office, Telephone (717) 782-4036.

#### SUPPLEMENTARY INFORMATION:

#### I. Public Comment Procedures

In accordance with the provisions of 30 CFR 884.15, OSM is seeking comment on whether the amendment proposed by Pennsylvania satisfies the applicable requirements for the approval of State program amendments. If the amendment is deemed adequate, it will become part of the Pennsylvania program.

#### Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Harrisburg Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

#### Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by close of business on October 6, 1998. Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment and who wish to do so will be heard following those scheduled. The hearing will end after all persons who desire to comment have been heard.

#### II. Procedural Determinations

##### Executive Order 12866

This proposed rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

##### Executive Order 12988

The Department of the Interior has conducted the reviews required by

section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

#### *National Environmental Policy Act*

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

#### *Paperwork Reduction Act*

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 et seq.).

#### *Regulatory Flexibility Act*

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions in the analyses for the corresponding Federal regulations.

#### *Unfunded Mandates*

This rule will not impose a cost of \$100 million or more in any given year on any governmental entity or the private sector.

#### **List of Subjects in 30 CFR Part 938**

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 18, 1998.

**Ronald C. Recker,**

*Acting Regional Director, Appalachian Regional Coordinating Center.*

[FR Doc. 98-25673 Filed 9-24-98; 8:45 am]

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## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 52**

[CA172-0103; FRL-6169-1]

#### **Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve a revision to the California State Implementation Plan (SIP) that concerns the control of criteria pollutants.

The intended effect of proposing approval of this rule is to regulate emissions of criteria pollutants in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). EPA has evaluated this rule and is proposing to approve it 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.

**DATES:** Comments must be received on or before October 26, 1998.

**ADDRESSES:** Comments may be mailed to: Erica Ruhl, Permits Office, (AIR-3), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

A copy of the rule and EPA's evaluation report of the rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule are also available for inspection at the following locations:

California Air Resources Board, 2020 L Street, Sacramento, CA 95812  
South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765.

#### **FOR FURTHER INFORMATION CONTACT:**

Erica Ruhl, Permits Office (AIR-3), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901, (415) 744-1171.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Applicability**

The rule being proposed for approval into the California SIP is South Coast Air Quality Management District ("SCAQMD" or "the District"), Rule 518.2, Federal Alternative Operating Conditions. This rule was adopted on January 12, 1996 and was submitted by the California Air Resources Board to EPA on May 10, 1996. This rule was found to be complete on July 19, 1996 pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51, appendix V<sup>1</sup> and is being proposed for approval into the SIP.

##### **II. Background**

California state law includes provisions for the granting of variances from air pollution control requirements. When granted, a variance protects a source from enforcement under California law. Historically, EPA has not recognized variances issued pursuant to state law and has taken the position that such variances do not shield sources from enforcement under federal law. If, however, a variance is submitted to EPA and is found to meet the substantive requirements of the Clean Air Act (CAA) governing SIP revisions, it can be approved as a revision to the SIP, thereby receiving federal recognition. State and federal law have coexisted in this manner for many years.

The Clean Air Act allows EPA 18 months to act on submitted SIP revisions<sup>2</sup> and often, because of a large backlog, the Agency takes that long to process them. Members of the regulated community have complained that this method for recognizing variances federally is too time consuming and complex. With this rule, The South Coast Air Quality Management District ("South Coast" or "the District") is proposing to make federal recognition of variances more expeditious by using the title V permitting process.

South Coast Rule 518.2 is designed to allow federal recognition of variances through a process that meets the procedural requirements pertaining to SIP revisions as well as the substantive requirements of the Clean Air Act. In a

<sup>1</sup> EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

<sup>2</sup> 42 U.S.C. 7410(k), CAA section 110(k).