

will be discussed at a public meeting to be held on May 21, 2002, from 9 a.m. to 4:30 p.m., at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the preliminary draft proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. The preliminary draft proposed rule and the comments submitted to this docket may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm> or www.fda.gov/cder/fdama under "Section 121—PET (Positron Emission Tomography)."

(Authority: 21 U.S.C. 321 *et seq.*)

Dated: March 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-7728 Filed 3-29-02; 8:45 am]

BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WY-001-0007b, WY-001-0008b, WY-001-0009b; FRL-7166-3]

Approval and Promulgation of Air Quality Implementation Plans; Wyoming; Withdrawal of Proposed Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of proposed rule.

SUMMARY: Due to the State of Wyoming's withdrawal of the August 9, 2000, August 7, 2001 and August 13, 2001 submittals to the EPA that revise the Wyoming State Implementation Plan (SIP), EPA is withdrawing the proposed rule, published concurrently with a direct final rule, to partially approve and partially disapprove these revisions that restructure and modify the State's air quality rules. In the direct final rule, published on February 6, 2002 (67 FR 5485), we stated that if we received

adverse comment by March 8, 2002, the rule would be withdrawn and would not take effect. EPA subsequently received a letter from the State of Wyoming (on March 8, 2002) withdrawing the three submittals that EPA is taking action on in our February 6, 2002 direct final rule. EPA also received adverse comments from the Wyoming Outdoor Council (on March 7, 2002). Since, in addition to receiving adverse comments, the State of Wyoming withdrew their submittals, the proposed rule and the direct final rule are withdrawn and will not take effect. In the "Final Rules" section of today's **Federal Register** publication, we are withdrawing the direct final rule published on February 6, 2002 (67 FR 5552).

EFFECTIVE DATE: The proposed rule is withdrawn as of April 1, 2002.

FOR FURTHER INFORMATION CONTACT: Megan Williams, EPA Region VIII, (303) 312-6431 or Laurel Dygowski, EPA Region VIII, (303) 312-6144.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule located in the Rules and Regulations section of the February 6, 2002 **Federal Register** (67 FR 5485).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen Dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, and Volatile organic compounds.

Dated: March 25, 2002.

Jack W. McGraw,

Acting Regional Administrator, Region VIII.

[FR Doc. 02-7773 Filed 3-29-02; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 255-0320a; FRL-7164-8]

Revisions to the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing both a conditional approval and a limited approval and limited disapproval of revisions to the San Joaquin Valley Unified Air Pollution Control District

(SJVUAPCD or District) portion of the California State Implementation Plan (SIP). These revisions concern fugitive dust and particulate matter less than 10 microns in diameter (PM-10). We are proposing action on local rules that regulate these emissions under the Clean Air Act, as amended in 1990 (CAA or the Act). The proposed conditional approval is with respect to enforceability and reasonably available control measures (RACM), and the proposed limited approval and limited disapproval is with respect to best available control measures (BACM). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by May 31, 2002.

ADDRESSES: Mail comments to Andy Steckel, Rulemaking Office Chief (AIR-4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

You can inspect copies of the submitted rule revisions and EPA's technical support document (TSD) at our Region IX office during normal business hours. You may also see copies of the submitted rule revisions and TSD at the following locations:

California Air Resources Board,
Stationary Source Division, Rule Evaluation Section, 1001 "I" Street, Sacramento, CA 95814.
San Joaquin Valley Unified Air Pollution Control District, 1990 East Gettysburg Street, Fresno, CA 93726.

FOR FURTHER INFORMATION CONTACT: Karen Irwin, Planning Office (AIR-2), U.S. Environmental Protection Agency, Region IX; (415) 947-4116.

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us" and "our" refer to EPA.

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I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules we are proposing to approve with the dates that they were adopted by the District and submitted by the California Air Resources Board (CARB) to EPA.

TABLE 1.—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
SJVUAPCD	8011	General Requirements	11/15/01	12/06/01
SJVUAPCD	8021	Construction, Demolition, Excavation, Extraction and Other Earthmoving Activities	11/15/01	12/06/01
SJVUAPCD	8031	Bulk Materials	11/15/01	12/06/01
SJVUAPCD	8041	Carryout and Trackout	11/15/01	12/06/01
SJVUAPCD	8051	Open Areas	11/15/01	12/06/01
SJVUAPCD	8061	Paved and Unpaved Roads	11/15/01	12/06/01
SJVUAPCD	8071	Unpaved Vehicle/Equipment Traffic Areas	11/15/01	12/06/01
SJVUAPCD	8081	Agricultural Sources	11/15/01	12/06/01

On January 22, 2002, EPA found that these submittals meet the completeness criteria in 40 CFR part 51, appendix V.

B. Are there other versions of these rules?

We approved prior versions of most of the submitted rules into the SIP on March 8, 2000 (65 FR 12188) with a

limited approval and limited disapproval rulemaking. Table 2 summarizes source category coverage of the submitted rules compared to the applicable SIP rules.

TABLE 2.—SIP AND SUBMITTED RULE COMPARISON

Fugitive dust source	Applicable SIP rule	Submitted rule
General Requirements	8010	8011
Construction, Demolition, Excavation, Extraction	8020	8021
Bulk Materials	8030	8031
Landfills	8040	8021
Carryout/Trackout	8020, 8030, 8040, 8070	8041
Open Areas	NA	8051
Paved and Unpaved Roads	8060	8061
Vehicle/Equipment Parking Areas	8070	8071
Agricultural Sources	NA	8081

C. What is the purpose of the submitted rule revisions?

The purpose of the submitted rules is to remedy deficiencies described in EPA's limited approval and limited disapproval of SIP Rules 8010, 8020, 8030, 8040, 8060 and 8070 on March 8, 2000. SJVUAPCD also submitted the revised rules to fulfill BACM requirements in CAA section 189.

II. EPA's Evaluation and Action

A. How is EPA evaluating the rules?

Generally, SIP rules must be enforceable (see section 110(a) of the CAA) and must not relax existing requirements (see section 110(l) and section 193). We evaluated these criteria using the CAA as amended in 1990, 40 CFR part 51, and various EPA policy and guidance documents. In addition, section 172(c)(1) and section 189(a) of the CAA require moderate PM-10 nonattainment areas to adopt RACM and section 189(b) of the CAA requires serious PM-10 nonattainment areas, including SJVUAPCD, to adopt BACM.

Guidance for RACM and BACM, respectively, includes the following:

- *General Preamble for the Implementation of Title I of the Clean*

Air Act Amendments of 1990 (57 FR 13498 and 13540, April 16, 1992).

- *Addendum to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990* (59 FR 41998, August 16, 1994).

B. Do the rules meet the evaluation criteria?

We believe relevant requirements in CAA section 110(a), section 110(l) and section 193 have been met because these rules are enforceable and more stringent overall than the existing SIP, which contains the District's 1996 adopted version of Regulation VIII. The District significantly strengthened Regulation VIII with the following requirements:

- Tightened general performance standard from 40% opacity to 20% opacity;
- Added requirements for existing (as opposed to 1993 and later) public access unpaved roads, including agricultural unpaved access roads, where none existed previously;
- Added surface stabilization standards and corresponding test methods for unpaved roads/unpaved traffic/equipment areas and disturbed surfaces;

- Added coverage of weed abatement activities and related surface disturbances where none existed previously;

- Added requirements for Dust Control Plans for certain construction, demolition, excavation, and extraction sites where none existed previously;

- Eliminated a 7-day allowance before inactive disturbed surface areas at construction, demolition, excavation and extraction sites are subject to control;

- Eliminated an option allowing a 24-hour period before trackout controls are required for sites subject to Rule 8041;

- Added a requirement for trackout extending 50 feet or more to be cleaned up immediately;

- Added a requirement for trackout control devices or paved interior roads for certain sites where none existed previously;

- Added coverage of agricultural unpaved traffic/equipment areas where none existed previously;

- Added coverage of off-field open area agricultural materials where none existed previously;

- Expanded coverage of bulk material requirements from ≥ 250 cubic yards of material to ≥ 100 cubic yards of material;

- Removed an exemption for unpaved roads or road segments <1/2 mile in length;

- Removed control measure options for unpaved roads that limit applicability of requirements to the entire length of the road;

- Added requirements for unpaved roads and inactive disturbed areas (not associated with the spreading of landfill daily cover) at landfills;

- Removed an exemption for paved road segments <3 miles in length from shoulder stabilization requirements for new/modified paved roads;

- Removed several other exemptions that potentially weakened rule coverage.

Because the version of Regulation VIII submitted on December 6, 2001 includes the types of measures commonly relied upon for achieving the bulk of PM-10 emission reductions from fugitive dust sources (e.g. stabilizing unpaved roads and unpaved parking/traffic areas, etc.) and because rule coverage for the significant source categories subject to Regulation VIII was significantly expanded, it is more likely than not that the regulation fulfills the requirements in CAA section 189(a) regarding RACM. However, the District has not completely fulfilled the requirement described in 57 FR 13498 and 13540 (April 16, 1992) to demonstrate that it has applied RACM to the significant source categories that are subject to Regulation VIII. By letter dated March 5, 2002, SJVUAPCD committed to fulfill this requirement by submitting a RACM demonstration to EPA within one year after the date of publication of final EPA action on this proposed rule. This commitment includes the following: (1) A complete list of candidate RACM for the following Regulation VIII significant sources: unpaved roads, unpaved vehicle/equipment traffic areas, paved roads and earthmoving sources, including bulk materials storage/handling; (2) a reasoned justification for any candidate measures that the District did not adopt for these sources, including descriptions of measures for these source categories that the District is implementing outside the context of Regulation VIII; and (3) information that supports the reasonableness of the Regulation VIII coverage.

In our prior proposed rulemaking (64 FR 51489, September 23, 1999), and subsequent final rulemaking (65 FR 12118, March 8, 2000) on Regulation VIII, we issued a limited approval and limited disapproval because of deficiencies in the submission. We established a sanctions clock under section 179 because the prior submission did not fulfill enforceability

requirements pursuant to section 110(a) or demonstrate RACM pursuant to section 189(a). We also discussed deficiencies regarding section 189(b) because the prior submission did not demonstrate BACM. We did not, however, start a sanction clock for section 189(b) deficiencies because the District explicitly adopted the April 25, 1996, Regulation VIII rules for purposes of maintaining RACM, rather than for meeting BACM requirements. We have now concluded that the District's December 6, 2001 submittal corrected the enforceability and RACM deficiencies that were the basis for the sanction clock.

At the time of our March 2000 action, we could have made a finding of failure to submit rules constituting BACM pursuant to section 179(a). However, the District has now corrected this failure to submit because it submitted Regulation VIII for the stated purpose of meeting BACM on December 6, 2001. Now that the District has submitted Regulation VIII for BACM purposes, EPA has evaluated the December 6, 2001 version of Regulation VIII for BACM. EPA believes that the submittal does not adequately fulfill the section 189(b) requirement for a BACM demonstration, nor any upgrades or revisions to the control measures that are required as a result of the BACM demonstration. EPA is proposing a limited approval and limited disapproval of the submittal with respect to BACM. If this proposal is finalized, it will start a sanction clock for the BACM deficiencies in the December 6, 2001 submittal.

The TSD accompanying this proposal provides more information on our evaluation of the District's submittal and identifies how the District has addressed the enforceability and RACM deficiencies associated with our March 8, 2000 rulemaking. The TSD also provides more information about why the December 6, 2001 submittal of Regulation VIII does not fulfill BACM requirements.

C. Proposed Action and Public Comment

Today we propose to approve conditionally Rules 8011, 8021, 8031, 8041, 8061, 8071 and 8081 pursuant to CAA section 110(k)(4), with respect to section 172(c)(1) and section 189(a)(1)(C)¹. Thus, we have concluded that the December 6, 2001 submittal resolves the prior enforceability and RACM deficiencies identified in the March 8, 2000 final action, subject to one condition. The condition is for the

District to provide a comprehensive and adequate RACM demonstration for Regulation VIII in accordance with EPA policy and guidance documents. The SJVUAPCD has committed to provide this RACM demonstration within one year after the date of publication of the final action on this proposal. The conditional approval will be treated as a disapproval, with sanctions for section 189(a) immediately re-instated, if the SJVUAPCD fails to fulfill this commitment within the statutory one year period. The TSD associated with this proposed action provides more detail on our RACM evaluation.

Based on this proposed conditional approval, elsewhere in today's **Federal Register**, EPA has published an interim final determination which stays the existing section 179 offset sanction and defers the section 179 highway sanction triggered by EPA's final rulemaking on SJVUAPCD Rules 8010, 8020, 8030, 8040, 8060, and 8070 (65 FR 12118, March 8, 2000). EPA is staying and deferring these sanctions because the December 6, 2001 submittal corrects the previously identified enforceability and RACM deficiencies.

We further propose limited approval and limited disapproval of Rules 8011, 8021, 8031, 8041, 8051, 8061, 8071 and 8081 per section 110(k)(3) and section 301(a) with respect to section 189(b)(1)(B)². This is because the rules strengthen the SIP, but the State has not adequately demonstrated that they fulfill BACM requirements. The TSD associated with this proposed action provides more detail on our BACM evaluation. If finalized, this action would incorporate the submitted rules into the SIP, but sanctions will be imposed under section 179 of the Act unless EPA approves subsequent SIP revisions that correct the Regulation VIII BACM deficiencies as identified in the TSD within 18 months of final action. These sanctions would be imposed according to 40 CFR 52.31. A final disapproval would also trigger the FIP requirement under section 110(c). Note that the submitted rules have been adopted by the SJVUAPCD, and EPA's final limited disapproval would not prevent the local agency from enforcing them.

We will accept comments from the public on this proposal for the next 60 days. Unless we receive convincing new information during the comment period, we intend to publish a final action that will incorporate these rules into the federally enforceable SIP.

¹ CAA section 189(a)(1)(C) requires Reasonably Available Control Measures.

² CAA section 189(b)(1)(B) requires Best Available Control Measures.

III. Background Information

Why Were These Rules Submitted?

PM-10 harms human health and the environment. Section 110(a) of the CAA

requires states to submit regulations that control PM-10 emissions. Table 3 lists some of the national milestones leading

to the submittal of local agency rules that help control PM-10 emissions.

TABLE 3.—PM-10 NONATTAINMENT MILESTONES

Date	Event
March 3, 1978	EPA promulgated a list of total suspended particulate (TSP) nonattainment areas under the CAA, as amended in 1977 (43 FR 8964; 40 CFR 81.305).
July 1, 1987	EPA replaced the TSP standards with new PM-10 standards (52 FR 24672).
November 15, 1990	CAA Amendments of 1990 were enacted, Pub. L. 101-549, 104 Stat. 2399, codified at 42 U.S.C. 7401-7671q.
November 15, 1990	PM-10 areas meeting the qualifications of section 107(d)(4)(B) of the CAA were designated non-attainment by operation of law and classified as moderate or serious pursuant to section 189(a) or section 189(b). States are required by section 110(a) to submit rules regulating PM-10 emissions in order to achieve the attainment dates specified in section 188(c).

IV. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 32111, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies 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.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in

Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045, “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA’s role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule

cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 31, 2002. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: March 20, 2002.

Wayne Nastri,

Regional Administrator, Region IX.

[FR Doc. 02-7634 Filed 3-29-02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL-7165-1]

Ocean Dumping; Proposed Site Designation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA today proposes to designate a new Ocean Dredged Material Disposal Site (ODMDS) in the