

Counsel, Food and Drug Administration, p. 1, dated July 16, 2002.

3. Letter from Margaret M. Dotzel, Associate Commissioner for Policy, Food and Drug Administration, to Peter Barton Hutt, Covington and Burling, July 22, 2002.

**IV. Request For Comments**

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This ANPRM is issued under section 201 et al. of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et al.) and under authority of the Commissioner of Food and Drugs.

Dated: April 21, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-12271 Filed 5-28-04; 8:45 am]

**BILLING CODE 4160-01-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[CA250-0453; FRL-7668-3]

**Disapproval of State Implementation Plan Revisions, Monterey Bay Unified Air Pollution Control District**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to disapprove a revision to the Monterey Bay Unified Air Pollution Control District (MBUAPCD) portion of the California State Implementation Plan (SIP) concerning excess emissions during breakdown. We are proposing action on a local rule that regulates these emissions under the Clean Air Act as amended in 1990 (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

**DATES:** Any comments must arrive by July 1, 2004.

**ADDRESSES:** Send comments to Andrew Steckel, Rulemaking Office Chief (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105 or e-mail to [steckel.andrew@epa.gov](mailto:steckel.andrew@epa.gov), or submit comments at <http://www.regulations.gov>.

You can inspect copies of the submitted rule revisions, EPA's technical support document (TSD), and public comments at our Region IX office during normal business hours by

appointment. You may also see copies of the submitted rule revisions by appointment at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 "I" Street, Sacramento, CA 95814.

Monterey Bay Unified Air Pollution Control District, 24580 Silver Cloud Court, Monterey, CA 93940.

A copy of the rule may also be available via the Internet at <http://www.arb.ca.gov/drdb/drdbltxt.htm>. Please be advised that this is not an EPA Web site and may not contain the same version of the rule that was submitted to EPA.

**FOR FURTHER INFORMATION CONTACT:** Thomas C. Canaday, EPA Region IX, (415) 947-4121, [canaday.tom@epa.gov](mailto:canaday.tom@epa.gov).

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

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**I. The State's Submittal**

*A. What Rule Did the State Submit?*

Table 1 lists the rule proposed for disapproval with the date that it was adopted and submitted by the California Air Resources Board (CARB).

**TABLE 1.—SUBMITTED RULE**

Local agency	Rule No.	Rule title	Adopted	Submitted
MBUAPCD .....	214	Breakdown Condition .....	03/21/01	10/30/01

On January 18, 2002, we determined that the rule submittal in Table 1 met the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.

*B. Are There Other Versions of This Rule?*

We approved a version of MBUAPCD Rule 214 into the SIP on July 13, 1987.

*C. What Are the Changes in the Submitted Rule?*

Rule 214 establishes that MBUAPCD may elect to take no enforcement action against an owner or operator of any equipment which has violated an emission standard or operational

requirement provided that a breakdown has occurred and certain other conditions are met. The submitted revisions to MBUAPCD Rule 214 modify the rule's format and add clarifying language. The TSD has more information about this rule.

**II. EPA's Evaluation and Action**

*A. How Is EPA Evaluating the Rule?*

Generally, SIP rules must be enforceable (see section 110(a) of the Act), must require Reasonably Available Control Technology (RACT) for major sources in nonattainment areas (see section 182(a)(2)(A)), and must not relax

existing requirements (see sections 110(l) and 193).

Guidance and policy documents that we used to help evaluate specific enforceability requirements consistently include the following:

1. "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations," EPA, May 25, 1988 (the Bluebook).
2. "Guidance Document for Correcting Common VOC & Other Rule Deficiencies," EPA Region 9, August 21, 2001 (the Little Bluebook).
3. "State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup and Shutdown," EPA Office of Air and

Radiation, and EPA Office of Enforcement and Compliance Assurance, September 20, 1999 ("Excess Emissions Policy").

4. "Guidelines for Including State and Local Rules in SIPs," EPA Region IX, December 17, 1998. These guidelines were transmitted to the California Air Resources Board in a letter dated December 23, 1998, from David P. Howekamp, Director, Air Division, EPA Region IX, to Michael Kenny, Executive Officer, California Air Resources Board.

#### B. Does the Rule Meet the Evaluation Criteria?

The submitted SIP revisions conflict with section 110 and part D of the Act for the following reason. MBUAPCD Rule 214 describes how the district intends to apply its enforcement discretion in instances where facilities exceed emissions limits due to breakdown. As stated in EPA's Excess Emissions Policy, a State or EPA may exercise its enforcement discretion to refrain from taking an enforcement action where excess emissions result from sudden and unavoidable malfunctions caused by circumstances entirely beyond the control of the owner or operator. However, the September 20, 1999 policy also makes clear that EPA will not approve SIP revisions that allow a State director's decision to bar EPA's or citizens' ability to take enforcement action. Accordingly, were EPA to approve an enforcement discretion rule such as Rule 214, we would do so only while making clear that such action had no effect on EPA's or citizens' enforcement prerogatives. Under these circumstances, such a SIP revision would have no effect on the SIP. For this reason EPA considers it unproductive and potentially confusing to approve this enforcement discretion rule into the SIP.

#### C. Proposed Action and Public Comment

As authorized in sections 110(k)(3) of the Act, we are proposing a disapproval of the submitted MBUAPCD Rule 214. This is not a required SIP submittal, so this disapproval would have no sanction implications under CAA section 179 or FIP implications under CAA section 110(c).

We will accept comments from the public on the proposed disapproval for the next 30 days.

### III. Statutory and Executive Order Reviews

#### A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory

action from Executive Order 12866, entitled "Regulatory Planning and Review."

#### B. Paperwork Reduction Act

This rulemaking does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

#### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies 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 small governmental jurisdictions.

This rulemaking action will not have a significant impact on a substantial number of small entities because SIP disapprovals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply disapprove for inclusion in the SIP requirements that the State is already imposing. Therefore, because the Federal SIP disapproval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co., v. U.S. EPA*, 427 U.S. 246, 255-66 (1976); 42 U.S.C. 7410(a)(2).

#### D. Unfunded Mandates Reform Act

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 disapproval action proposed 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 Federal action proposes to disapprove pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

#### E. Executive Order 13132, Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that 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." Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rulemaking action will 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, because it merely disapproves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of

section 6 of the Executive Order do not apply to this rulemaking.

*F. Executive Order 13175, Coordination With Indian Tribal Governments*

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." These proposed rule disapproval does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, 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. Thus, Executive Order 13175 does not apply to this rule disapproval.

EPA specifically solicits additional comment on this proposed rule disapproval from tribal officials.

*G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks*

*Protection of Children From Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rulemaking on children, and explain why the planned action is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rulemaking is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

*H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use*

This rulemaking is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act*

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use "voluntary consensus standards" (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compound.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: May 19, 2004.

**Wayne Nastri,**

*Regional Administrator, Region IX.*

[FR Doc. 04-12303 Filed 5-28-04; 8:45 am]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[Docket Number: WA-04-001; FRL-7668-6]

**Approval and Promulgation of State Implementation Plans: Washington; Central Puget Sound Carbon Monoxide and Ozone Second 10-Year Maintenance Plans**

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

**ACTION:** Proposed rule.

**SUMMARY:** The EPA proposes to approve second 10-year maintenance plans for carbon monoxide (CO) and ozone for the Central Puget Sound area. Specifically, in this action EPA proposes to approve Washington's demonstration that the Central Puget Sound area will maintain air quality standards for CO and ozone through the year 2016; a revised CO motor vehicle emissions budget for transportation conformity purposes using the MOBILE6.2 emissions model and latest growth and planning assumptions; updates and enhancements of state implementation plan (SIP) control measures and contingency measures; and identification of emissions associated

with the Seattle-Tacoma International Airport included in the area-wide emissions inventory through the maintenance period.

**DATES:** Comments must be received on or before July 1, 2004.

**ADDRESSES:** Submit your comments, identified by Docket ID No. WA-04-001, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- E-mail: [R10aircom@epa.gov](mailto:R10aircom@epa.gov).

- Fax: (206) 553-0110.

- Mail: Office of Air Quality, Environmental Protection Agency Region 10, Mail code: OAQ-107, 1200 Sixth Ave., Seattle, Washington 98101.

- Hand Delivery: Environmental Protection Agency Region 10, Service Center, 14th Floor, 1200 Sixth Ave., Seattle, Washington 98101. Such deliveries are only accepted during normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to Docket ID No. WA-04-001. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov), or e-mail. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

**Docket:** Docket materials are publicly available in hard copy at the Office of Air Quality, Environmental Protection Agency, Mail code: OAQ-107, 1200