have a contractual relationship providing for such activities or share a common owner. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule II may be transmitted from a retail pharmacy to a central fill pharmacy via facsimile or a common, real-time electronic database. The retail pharmacy transmitting the prescription information must:

(1) Write the word ''CENTRAL FILL'' on the face of the original transmitted prescription, if sent via facsimile;

(2) Record and transmit to the central fill pharmacy (on the reverse side of the transmitted prescription, if sent via facsimile) the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the retail pharmacy from which transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(3) Ensure that all information required to be on a prescription pursuant to § 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(4) Maintain the original prescription for a period of two years from the date the prescription was filled;

(5) Keep a record of receipt of the filled prescription, including the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and the date of filling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common or contract carrier).

7. Section 1306.24 is proposed to be amended by redesignating the existing paragraphs (b) and (c) as paragraphs (c) and (d), and by adding a new paragraph (b) to read as follows:

§ 1306.24 Labeling of substances and filling of prescriptions.

* * * * *

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

* * * * *

8. Section 1306.26 is proposed to be amended by adding a new paragraph (g) to read as follows:

§ 1306.26 Dispensing without prescription.

* * * * *

(g) Central fill pharmacies shall not be permitted to dispense controlled substances to a purchaser at retail pursuant to this section.

9. A new § 1306.27 is proposed to be added to read as follows:

§ 1306.27 Transfer of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.

Prescription information may be transferred between a retail pharmacy and a central fill pharmacy for dispensing purposes only if permitted under state law and only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule III, IV or V may be transmitted from a retail pharmacy to a central fill pharmacy via facsimile or a common, real-time electronic database. The retail pharmacy transmitting the prescription information must:

(1) Write the word ''CENTRAL FILL'' on the face of the original transmitted prescription, if sent via facsimile;

(2) Record and transmit to the central fill pharmacy (on the reverse side of the transmitted prescription, if sent via facsimile) the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the retail pharmacy from which transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(3) Ensure that all information required to be on a prescription pursuant to Section 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(4) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

(5) Maintain the original prescription for a period of two years from the date the prescription was last refilled;

(6) Keep a record of receipt of the filled prescription, including the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common or contract carrier).

Dated: August 27, 2001.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 01–22322 Filed 9–5–01; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA041–4153; FRL–7049–7]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Reasonably Available Control Technology Requirements for Volatile Organic Compounds and Nitrogen Oxides in the Philadelphia-Wilmington-Trenton Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to remove the limited status of its approval of the Commonwealth of Pennsylvania State Implementation Plan (SIP) revision that requires all major sources of volatile organic compounds (VOC) and nitrogen oxides (NO_X) to implement reasonably available control technology (RACT) as it applies in the Philadelphia-Wilmington-Trenton ozone nonattainment area (the Philadelphia

area). EPA is proposing to convert its limited approval of Pennsylvania's VOC and NO_X RACT regulations to full approval because EPA has approved or is currently conducting rulemaking to approve all of the case-by-case RACT determinations submitted by Pennsylvania for the affected sources located in the Philadelphia area. The intended effect of this action is to remove the limited nature of EPA's approval of Pennsylvania's VOC and NO_X RACT regulations as they apply in the Philadelphia area.

DATES: Written comments must be received on or before October 9, 2001.

ADDRESSES: Written comments should be mailed to Marcia L. Spink, Associate Director, Office of Air Programs, Mailcode 3AP20, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103, and the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Marcia L. Spink, (215) 814-2104, at the EPA Region III address above, or by e-mail at *spink.marcia@epa.gov.* Please note that while questions may be posed via telephone and e-mail, formal comments must be submitted, in writing, as indicated in the **ADDRESSES** section of this document.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to sections 182(b)(2) and 182(f) of the Clean Air Act (CAA), the Commonwealth of Pennsylvania (the Commonwealth or Pennsylvania) is required to establish and implement RACT for all major VOC and NO_X sources. State implementation plan revisions imposing reasonably available control technology (RACT) for three classes of VOC sources are required under section 182(b)(2). The categories are all sources covered by a Control Technique Guideline (CTG) document issued between November 15, 1990 and the date of attainment; all sources covered by a CTG issued prior to November 15, 1990; and all other major non-CTG sources. Section 182(f) provides that the planning requirements applicable to major stationary sources of VOC in other provisions in part D, subpart 2 (including section 182) apply to major stationary sources of NO_X.

The Pennsylvania SIP already includes approved RACT regulations for sources and source categories of VOCs covered by the CTGs as required by section 182(b)(2)(A) and (B). Regulations requiring RACT for all major sources of VOC and NO_X were to be submitted to EPA as SIP revisions by November 15, 1992 and compliance required by May of 1995. On February 4, 1994, PADEP submitted a revision to its SIP consisting of 25 Pa Code Chapters 129.91 through 129.95 to require major sources of NO_X and additional major sources of VOC emissions (not covered by a CTG) to implement RACT (non-CTG RACT rules). The February 4, 1994 submittal was amended on May 3, 1994 to correct and clarify certain presumptive NO_X RACT requirements under Chapter 129.93. As described in more detail below, EPA granted conditional limited approval of the Commonwealth's VOC and NO_X RACT regulations on March 23, 1998 (63 FR 13789), and removed the conditional aspect of the approval on May 3, 2001 (66 FR 22123).

Under section 184 of the CAA, RACT as specified in sections 182(b)(2) and 182(f)) applies throughout the ozone transport region (OTR). The entire Commonwealth is located within the OTR. Therefore, RACT is applicable statewide in Pennsylvania. The major source size generally is determined by the classification of the area in which the source is located. However, for areas located in the OTR, the major source size for stationary sources of VOC is 50 tons per year (tpy) unless the area's classification prescribes a lower major source threshold. In the Philadelphia area, which is classified as severe, a major source of VOC is defined as one having the potential to emit 25 tpy or more, and a major source of NO_X is also defined as one having the potential to emit 25 tpy or more. In the Philadelphia area, Pennsylvania's RACT regulations require non-CTG sources that have the potential to emit 25 tpy or more of VOC and sources which have the potential to emit 25 tpy or more of NO_X comply with RACT. The regulations contain technology-based or operational ''presumptive RACT emission limitations'' for certain major NO_X sources. For other major NO_X sources, and all major non-CTG VOC sources (not otherwise already subject to RACT pursuant to a source category regulation under the Pennsylvania SIP), the regulations contain a ''generic'' RACT provision. A generic RACT regulation is one that does not, itself, specifically define RACT for a source or source categories but instead allows for case-by-case RACT determinations. The generic provisions of Pennsylvania's regulations allow for PADEP to make case-by-case RACT determinations that are then to be submitted to EPA as revisions to the Pennsylvania SIP.

On March 23, 1998, EPA granted conditional limited approval to the Commonwealth's generic VOC and NO_X RACT regulations (63 FR 13789). In that action, EPA stated that the conditions of its approval would be satisfied once the Commonwealth either (1) certifies that it has submitted case-by-case RACT proposals for all sources subject to the RACT requirements currently known to PADEP; *or* (2) demonstrates that the emissions from any remaining subject sources represent a de minimis level of emissions as defined in the March 23, 1998 rulemaking.

On April 22, 1999, PADEP made the required submittal to EPA, certifying that it had met the terms and conditions imposed by EPA in the conditional limited approval by submitting 485 case-by-case VOC/ NO_X RACT determinations as SIP revisions and making the demonstration described as condition 2, above. On May 3, 2001 (66 FR 22123), EPA published a rulemaking determining that Pennsylvania had satisfied the conditions imposed in its conditional limited approval. Thus, in that rulemaking, EPA removed the conditional status of its approval of the Commonwealth's generic VOC and NO_X RACT regulations on a statewide basis. The final rule removing the conditional status of Pennsylvania's VOC and NO_X RACT regulations became effective on June 18, 2001. As of that time, Pennsylvania's generic VOC and NO_X RACT regulations retained a limited approval status.

It should be noted that the Commonwealth has adopted and is implementing additional ''post RACT requirements'' to reduce seasonal NO_X emissions in the form of a NO_X cap and trade regulation, 25 Pa Code Chapters 121 and 123, based upon a model rule developed by the States in the OTR. That rule's compliance date is May 1999. That regulation was approved as SIP revision on June 6, 2000 (65 FR 35842). This SIP-approved regulation is more stringent than the case-by-case RACT determinations submitted by Pennsylvania for the affected sources in that it requires more total reductions in NO_X emissions from that group of sources than does their combined case-by-case RACT submittals. Pennsylvania has also adopted regulations to satisfy Phase I of the NO_X SIP call and submitted those regulations to EPA for SIP approval. Pennsylvania's SIP revision to address the requirements of

the NO_X SIP Call Phase I consists of the adoption of Chapter 145—Interstate Pollution Transport Reduction and amendments to Chapter 123—Standards for Contaminants. On May 29, 2001 (66 FR 29064), EPA proposed approval of the Commonwealth's NO_X SIP call rule SIP submittal. On August 21, 2001 (66 FR 43795), EPA published its final rule approving the Commonwealth's NO_X SIP call rule SIP submittal. Subsequent Federal approval of a case-by-case RACT determination for a major source of NO_X in no way relieves that source from any applicable, and previously SIP-approved, requirements found in 25 PA Code Chapters 121, 123 and 145.

II. EPA's Action

As EPA stated in its May 3, 2001 final rule (66 FR 22123), conversion from limited to full approval would occur when EPA has approved the case-by-case RACT determinations submitted by PADEP to satisfy the condition imposed by EPA in its March 23, 1998 (63 FR 13789) final rule. EPA has approved or is currently conducting rulemaking to approve all of the case-by-case RACT determinations submitted by PADEP to satisfy the condition imposed in EPA's March 23, 1998 (63 FR 13789) final rule for affected major sources of NO_X and/or VOC sources located in Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties, the five counties that comprise the Pennsylvania portion of the Philadelphia area.

Proposed Action

EPA is proposing to convert its limited approval of Pennsylvania's generic VOC and NO_X RACT regulations, 25 Pa Code Chapter 129.91 through 129.95, to full approval as they apply in the five-county Pennsylvania portion of the Philadelphia-Wilmington-Trenton ozone nonattainment area. EPA has approved or is currently conducting rulemaking to approve all of the case-by-case RACT determinations submitted by PADEP to satisfy the condition imposed in EPA's March 23, 1998 (63 FR 13789) final rule for affected major sources of NO_X and/or VOC sources located in Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties, the five counties that comprise the Pennsylvania portion of the Philadelphia area. Final action converting the limited approval to full approval shall occur once EPA has completed rulemaking to approve either (1) the case-by-case RACT proposals for all sources subject to the RACT requirements currently known in the Philadelphia area, *or* (2) for a sufficient number of sources such that the emissions from any remaining subject sources represent a de minimis level of emissions as defined in the March 23, 1998 rulemaking (63 FR 13789) .

III. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed 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 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed 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 proposes to approve 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 proposed rule also does 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), nor will it 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), because it merely proposes to approve 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. This proposed rule also is not subject to Executive Order 13045 (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 Clean Air Act. 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 Clean Air Act. 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. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings' issued under the executive order. This proposed rule regarding Pennsylvania's generic VOC and NO_X RACT regulations as they apply in the Philadelphia area does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Nitrogen dioxide, Ozone.

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

Dated: August 29, 2001.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 01–22362 Filed 9–5–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA–4135b; FRL–7049–6]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; VOC and NO_X RACT Determinations for 14 Individual Sources in the Philadelphia-Wilmington-Trenton Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revisions submitted by the Commonwealth of Pennsylvania for the purpose of establishing and requiring reasonably available control technology