

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 October 23, 2007. 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) of the CAA.)

List of Subjects in 40 CFR Part 52

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

Dated: August 16, 2007.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart S—Kentucky

■ 2. Section 52.920(e) is amended by revising the entry for "Louisville 8-hour Ozone Maintenance Plan" to read as follows:

§ 52.920 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED KENTUCKY NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Louisville 8-hour Ozone Maintenance Plan	Bullitt County, Jefferson County, Oldham County.	09/26/2006	07/05/07, 72 FR 36601.	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA-R03-OAR-2007-0175; FRL-8459-3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Redesignation of the Reading 8-Hour Ozone Nonattainment Area to Attainment and Approval of the Area's Maintenance Plan and 2002 Base-Year Inventory

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a redesignation request and State Implementation Plan (SIP) revisions submitted by the Commonwealth of Pennsylvania. The Pennsylvania Department of Environmental Protection

(PADEP) is requesting that the Reading, Berks County, Pennsylvania ozone nonattainment area (Reading Area) be redesignated as attainment for the 8-hour ozone national ambient air quality standard (NAAQS). In conjunction with its redesignation request, the PADEP submitted SIP revisions consisting of a maintenance plan for the Reading Area that provides for continued attainment of the 8-hour ozone NAAQS for at least 10 years after redesignation. EPA is approving the 8-hour maintenance plan. PADEP also submitted a 2002 base-year inventory for the Reading Area which EPA is approving. In addition, EPA is approving the adequacy determination for the motor vehicle emission budgets (MVEBs) that are identified in the Reading Area maintenance plan for purposes of transportation conformity, and is approving those MVEBs. EPA is approving the redesignation request, and the maintenance plan, and the 2002 base-year emissions inventory as revisions to the Pennsylvania SIP in accordance with the requirements of the Clean Air Act.

DATES: *Effective Date:* This final rule is effective on September 10, 2007.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2007-0175. All documents in the docket are listed in the www.regulations.gov website. Although listed in the electronic docket, some information is not publicly available, *i.e.*, confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy 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. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality

Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Christopher Cripps, (215) 814-2179, or by e-mail at cripps.christopher@epa.gov.
SUPPLEMENTARY INFORMATION:

I. Background

On May 30, 2007 (72 FR 29901), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Pennsylvania. The NPR proposed approval of Pennsylvania's redesignation request, a SIP revision that establishes a maintenance plan for the Reading Area that provides for continued attainment of the 8-hour ozone NAAQS for at least 10 years after redesignation, and a 2002 base-year emissions inventory. The formal SIP revisions were submitted by PADEP on January 25, 2007. Other specific requirements of Pennsylvania's redesignation request and SIP revision for the maintenance plan, and the rationale for EPA's proposed actions are explained in the NPR and will not be restated here.

On December 22, 2006, the U.S. Court of Appeals for the District of Columbia Circuit vacated EPA's Phase 1 Implementation Rule for the 8-hour Ozone Standard (69 FR 23951, April 30, 2004). *South Coast Air Quality Management Dist. v. EPA*, 472 F.3d 882 (D.C. Cir. 2006). On June 8, 2007, in *South Coast Air Quality Management Dist. v. EPA*, Docket No. 04-1201, in response to several petitions for rehearing, the D.C. Circuit clarified that the Phase 1 Rule was vacated only with regard to those parts of the rule that had been successfully challenged. Therefore, the Phase 1 Rule provisions related to classifications for areas currently classified under subpart 2 of Title I, part D of the Act as 8-hour nonattainment areas, the 8-hour attainment dates, and the timing for emissions reductions needed for attainment of the 8-hour ozone NAAQS remain effective. The June 8 decision left intact the Court's rejection of EPA's reasons for implementing the 8-hour standard in certain nonattainment areas under subpart 1 in lieu of subpart 2. By limiting the vacatur, the Court let stand EPA's revocation of the 1-hour standard and those anti-backsliding provisions of the Phase 1 Rule that had not been successfully challenged. The June 8, 2007 decision reaffirmed the December 22, 2006 decision that EPA had improperly failed to retain four measures required for 1-hour nonattainment areas under the anti-backsliding provisions of the regulations: (1) Nonattainment area

nonattainment New Source Review (NSR) requirements based on an area's 1-hour nonattainment classification; (2) Section 185 penalty fees for 1-hour severe or extreme nonattainment areas; and (3) measures to be implemented pursuant to section 172(c)(9) or 182(c)(9) of the Act, on the contingency of an area not making reasonable further progress toward attainment of the 1-hour NAAQS, or for failure to attain that NAAQS. In addition the June 8, 2007 decision clarified that the Court's reference to conformity requirements for anti-backsliding purposes was limited to requiring the continued use of 1-hour motor vehicle emissions budgets until 8-hour budgets were available for 8-hour conformity determinations, which is already required under EPA's conformity regulations. The Court thus clarified that 1-hour conformity determinations are not required for anti-backsliding purposes.

For the reasons set forth in the May 30, 2007 (72 FR 29901) proposed rulemaking, EPA does not believe that the Court's rulings alter any requirements relevant to this redesignation action so as to preclude redesignation, and do not prevent EPA from finalizing this redesignation. EPA believes that the Court's December 22, 2006 and June 8, 2007 decisions impose no impediment to moving forward with the redesignation of this Area to attainment, because even in light of the Court's decisions, redesignation is appropriate under the relevant redesignation provisions of the Act and longstanding policies regarding redesignation requests.

With respect to the requirement for transportation conformity under the 1-hour standard, the Court in its June 8, 2007 decision clarified that for those areas with 1-hour motor vehicle emissions budgets in their 1-hour maintenance plans, anti-backsliding requires only that those 1-hour budgets must be used for 8-hour conformity determinations until replaced by 8-hour budgets. To meet this requirement, conformity determinations in such areas must continue to comply with the applicable requirements of EPA's conformity regulations at 40 CFR Part 93. As discussed elsewhere in this document, EPA is approving 8-hour MVEBs for the Reading Area. Approval of the 8-hour MVEBs means that the 1-hour budgets no longer apply under anti-backsliding. The court clarified that 1-hour conformity determinations are not required for anti-backsliding purposes.

II. Comments and EPA's Responses

EPA received one comment. The comment did not object to the proposed approvals of the redesignation request, maintenance plan or the 2002 base year inventory. The comment merely pointed out that EPA's notice had incorrectly identified the metropolitan planning organization (MPO) with jurisdiction over the Reading Area. EPA acknowledges that, as the commenter notes, we mistakenly identified the MPO as the "Northern Tier RPO" in the notice. The MPO, however, is identified correctly in the maintenance plan for the Reading Area (Berks County). The reference to the "Northern Tier RPO" on page 29911 of the May 30, 2007 notice therefore should have been to Reading Metropolitan Planning Organization ("Berks County MPO").

III. Effective Date

EPA finds that there is good cause for this redesignation to attainment, and SIP revisions to become effective fifteen days after publication because a more delayed effective date is unnecessary due to the nature of a redesignation to attainment which relieves the area from certain Clean Air Act requirements that would otherwise apply to it. The effective date for this redesignation is authorized under both 5 U.S.C. 553(d)(1), which provides that rulemaking actions may become effective less than 30 days after publication if the rule "grants or recognizes an exemption or relieves a restriction" and section 553(d)(3), which allows an effective date less than 30 days after publication "as otherwise provided by the agency for good cause found and published with the rule."

IV. Final Actions

EPA is approving the Commonwealth of Pennsylvania's redesignation request, maintenance plan, and the 2002 base-year emissions inventory because the requirements for approval have been satisfied. EPA has evaluated Pennsylvania's redesignation request that was submitted on January 25, 2007, and determined that it meets the redesignation criteria set forth in section 107(d)(3)(E) of the Clean Air Act. EPA believes that the redesignation request and monitoring data demonstrate that the Reading Area has attained the 8-hour ozone standard. The final approval of this redesignation request will change the designation of the Reading Area from nonattainment to attainment for the 8-hour ozone standard. EPA is approving the maintenance plan for the Reading Area submitted on January 25, 2007 as a revision to the Pennsylvania

SIP. EPA is also approving the MVEBs submitted by PADEP in conjunction with its redesignation request. In addition, EPA is approving the 2002 base-year emissions inventory submitted by PADEP on January 25, 2007, as a revision to the Pennsylvania SIP. In this final rulemaking, EPA is notifying the public that we have found that the MVEBs for nitrogen oxides (NO_x) and volatile organic compound (VOC) emissions in the Reading Area for the 8-hour ozone maintenance plan are adequate and approved for conformity purposes. As a result of our finding, the Reading Area must use the MVEBs from the submitted 8-hour ozone maintenance plan for future conformity determinations. The adequate and approved MVEBs are provided in the following table:

ADEQUATE AND APPROVED MOTOR VEHICLE EMISSIONS BUDGETS IN TONS PER DAY (TPD)

Budget year	NO _x	VOC
2009	22.3	14.3
2018	9.0	7.8

V. Statutory and Executive Order Reviews

A. General 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 13211, “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. Redesignation of an area to attainment under section 107(d)(3)(e) of the Clean Air Act does not impose any new requirements on small entities. Redesignation is an action that affects the status of a geographical area and does not impose any new regulatory requirements on sources. 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 (Pub. L. 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). Because this action affects the status of a geographical area or allows the state to avoid adopting or implementing other requirements and because this action does not impose any new requirements on sources, 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 requirement, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. 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 approves a state rule implementing a Federal standard.

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. Redesignation is an action that affects the status of a geographical area and does not impose any new requirements on sources. 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.*).

B. Submission to Congress and the Comptroller General

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**. This rule is not a “major rule” as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 23, 2007. 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, approving the redesignation of the Reading Area to attainment for the 8-hour ozone NAAQS, the associated maintenance plan, the 2002 base-year emissions inventory, and the MVEBs identified in the maintenance plan, may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Dated: August 9, 2007.

William T. Wisniewski,
Acting Regional Administrator, Region III.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart NN—Pennsylvania

■ 2. In § 52.2020, the table in paragraph (e)(1) is amended by adding an entry for

the 8-hour Ozone Maintenance Plan and the 2002 Base Year Emissions Inventory for the Reading, Pennsylvania Area at the end of the table to read as follows:

§ 52.2020 Identification of plan.
* * * * *
(e) * * *
(1) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
8-Hour Ozone Maintenance Plan and 2002 Base Year Emissions Inventory.	Reading Area (Berks County)	1/25/2007	8/24/2007 [Insert page number where the document begins].	

PART 81—[AMENDED]

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

■ 3. The authority citation for part 81 continues to read as follows:

■ 4. In § 81.339, the table entitled “Pennsylvania—Ozone (8-Hour Standard)” is amended by revising the

entry for the Reading, PA Area to read as follows:

§ 81.339 Pennsylvania.
* * * * *

PENNSYLVANIA—OZONE (8-HOUR STANDARD)

Designated area	Designation ^a		Category/classification	
	Date ¹	Type	Date ¹	Type
Reading, PA: Berks County	9/10/2007	Attainment.		

^a Includes Indian County located in each county or area, except otherwise noted.
¹ This date is June 15, 2004, unless otherwise noted.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS-3014-IFC]

RIN 0938-AJ29

Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period requires hospitals that transfuse blood and blood components to: Prepare and follow written procedures for appropriate action when it is determined that blood and blood

components the hospitals received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and extend the records retention period for transfusion-related data to 10 years.

These changes are based on recommendations by the Secretary’s Advisory Committee on Blood Safety and Availability and are being published in conjunction with the Food and Drug Administration’s (FDA) Final Rule, “Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection” (“lookback”) found elsewhere in this issue of the **Federal Register**. The intent is to aid in the prevention of HCV infection and to create opportunities for disease prevention that, in most cases, can

occur many years after recipient exposure to a donor.

DATES: *Effective Date:* These regulations are effective on February 20, 2008.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 23, 2007.

ADDRESSES: In commenting, please refer to file code CMS-3014-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link “Submit electronic comments on CMS regulations with an open comment period.” (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid