

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), 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."

This action does not have federalism implications. It 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 certain State requirements for inclusion into the SIP and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175, Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP EPA is proposing to disapprove would not apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act

will not in and of itself create any new regulations but simply disapproves certain State requirements for inclusion into the SIP.

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

This action is not subject to Executive Order 13211 (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(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA", Public Law No. 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through the Office of Management and Budget, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

EPA believes that this action is not subject to requirements of Section 12(d) of NTTAA because application of those requirements would be inconsistent with the Clean Air Act.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this proposed action. In reviewing SIP submissions, EPA's role is to approve or disapprove state choices, based on the criteria of the Clean Air Act. Accordingly, this action merely proposes to disapprove certain State requirements for inclusion into the SIP

under section 110 and subchapter I, part D of the Clean Air Act and will not in and of itself create any new requirements. Accordingly, it does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898.

In addition, this proposed rule pertaining to the Delaware 8-hour ozone attainment demonstration plan does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Nitrogen dioxide, Ozone, Incorporation by reference, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: April 28, 2009.

William C. Early,

Acting Regional Administrator, Region III.
[FR Doc. E9–10680 Filed 5–7–09; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2008–0928; FRL–8901–4]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Attainment Demonstration for the Philadelphia-Wilmington-Atlantic City Moderate 8-Hour Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to disapprove the ozone attainment demonstration portion of a comprehensive State Implementation Plan (SIP) revision submitted by the Pennsylvania Department of Environmental Protection (PADEP) to meet the Clean Air Act (CAA) requirements for attaining the 8-hour ozone national ambient air quality standard (NAAQS) for the five-county Pennsylvania portion of the Philadelphia-Wilmington-Atlantic City moderate nonattainment area

(Philadelphia Area). The five-county Pennsylvania portion of the Philadelphia Area comprises Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties. EPA is proposing to disapprove Pennsylvania's 8-hour ozone attainment demonstration plan for its portion of the Philadelphia Area because EPA has determined that the photochemical modeling does not demonstrate attainment, and the weight of evidence analysis that Pennsylvania uses to support the attainment demonstration, does not provide the sufficient evidence that the Philadelphia Area, will attain the NAAQS by the June 2010 deadline.

DATES: Written comments must be received on or before June 8, 2009.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2008-0928 by one of the following methods:

A. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *E-mail*:

fernandez.cristina@epa.gov.

C. *Mail*: EPA-R03-OAR-2008-0928, Cristina Fernandez, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery*: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2008-0928. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov*, 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* or e-mail. The *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*, 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: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., 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 in *www.regulations.gov* or in hard copy 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: Brian Rehn, (215) 814-2176, or by e-mail at *rehn.brian@epa.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. What Action Is EPA Proposing?
- II. What Are the CAA Requirements for a Moderate 8-Hour Ozone Nonattainment Area?
 - A. History and Time Frame for the State's Attainment Demonstration SIP
 - B. CAA Requirements
- III. What Was Included in Pennsylvania's SIP Submittals?
- IV. What Is EPA's Review of Pennsylvania's Modeled Attainment Demonstration and Weight of Evidence (WOE) Analysis for the Pennsylvania Portion of the Philadelphia Area?
- V. What Are the Consequences of a Disapproved SIP?
 - A. What Are the CAA's Provisions for Sanctions?
 - B. What Are the CAA's Federal Implementation Plan (FIP) Ramifications if a State Fails To Submit an Approvable Plan?
 - C. What Are the Ramifications Regarding Conformity?
- VI. What Is EPA's Conclusion?
- VII. Statutory and Executive Order Reviews
 - A. Executive Order 12866, Regulatory Planning and Review
 - B. Paperwork Reduction Act

- C. Regulatory Flexibility Act
- D. Unfunded Mandates Reform Act
- E. Executive Order 13132, Federalism
- F. Executive Order 13175, Coordination With Indian Tribal Governments
- G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks
- H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act
- J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. What Action is EPA Proposing?

EPA is proposing to disapprove the SIP revision consisting of the 8-hour ozone attainment demonstration for the five-county Pennsylvania portion of the Philadelphia Area. The Pennsylvania portion of the Philadelphia Area comprises Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties. This SIP revision was submitted by PADEP on August 29, 2007.

EPA is proposing to disapprove Pennsylvania's 8-hour ozone attainment demonstration plan for its portion of the Philadelphia Area because EPA has determined that the photochemical modeling does not demonstrate attainment, and the weight of evidence analysis that Pennsylvania uses to support the attainment demonstration, does not provide the sufficient evidence that the Philadelphia Area, will attain the NAAQS by the June 2010 deadline.

EPA's analysis and findings are discussed in this proposed rulemaking and a more detailed discussion is contained in the Technical Support Document (TSD) for this proposal which is available on line at *www.regulations.gov*, docket number EPA-R03-OAR-2008-0928.

II. What Are the CAA Requirements for a Moderate 8-Hour Ozone Nonattainment Area?

A. History and Time Frame for the State's Attainment Demonstration SIP

In 1997, EPA revised the health-based NAAQS for ozone, setting it at 0.08 parts per million (ppm) averaged over an 8-hour time frame ("8-hour ozone standard").¹ EPA set the 8-hour ozone standard based on scientific evidence demonstrating that ozone causes adverse health effects at lower ozone concentrations, and over longer periods

¹ In 2008, EPA promulgated a more stringent 8-hour standard of 0.075 ppm. 73 FR 16436 (March 27, 2008). All references to the 8-hour ozone standard in this rulemaking refer to the 8-hour standard promulgated in 1997.

of time, than was understood when the pre-existing 1-hour ozone standard was set. EPA determined that the 8-hour standard would be more protective of human health, especially children and adults who are active outdoors, and individuals with a pre-existing respiratory disease, such as asthma.

On April 30, 2004 (69 FR 23951), EPA finalized its attainment/nonattainment designations for areas across the country with respect to the 8-hour ozone standard. These actions became effective on June 15, 2004. In addition, EPA promulgated its Phase 1 Rule for implementation of the 8-hour standard, which provided how areas designated nonattainment for the 8-hour ozone standard would be classified. April 30, 2004 (69 FR 23951). Among those nonattainment areas is the Philadelphia Area. The Philadelphia Area includes three counties in Delaware, five counties in eastern Pennsylvania, one county in Maryland and eight counties in southern New Jersey. The Pennsylvania portion of the Philadelphia Area consists of the following counties: Bucks, Chester, Delaware, Montgomery, and Philadelphia. EPA's Phase 2 8-hour ozone implementation rule, published on November 29, 2005 (70 FR 71612) specifies that states must submit attainment demonstrations for their nonattainment areas to the EPA by no later than three years from the effective date of designation, that is, by June 15, 2007. *See*, 40 CFR 51.908(a).

B. CAA Requirements

Pursuant to Phase 1 of the 8-hour ozone implementation rule, published on April 30, 2004 (69 FR 23951), an area was classified under subpart 2 of Title I of the CAA based on its 8-hour design value if it had a 1-hour design value at or above 0.121 ppm. Based on this criterion, the Philadelphia Area was classified under subpart 2 as a moderate nonattainment area. On November 29, 2005 (70 FR 71612), EPA published the Phase 2 of the 8-hour ozone implementation rule in which it addresses the control obligations that apply to areas classified under subpart 2. Among other things, the Phase 1 and 2 rules outline the SIP requirements and deadlines for various requirements in areas designated as moderate nonattainment.

III. What Was Included in Pennsylvania's SIP Submittals?

On August 29, 2007, PADEP submitted a comprehensive 8-hour ozone SIP. The SIP submittal included an attainment demonstration plan, a reasonable further progress (RFP) plan,

reasonably available control measures analysis, contingency measures, on-road motor vehicle emission budgets, and 2002 base year emissions inventory for the five-county Pennsylvania portion of the Philadelphia Area. These SIP revisions were subject to notice and comment by the public and the State addressed the comments received on the proposed SIPs. Only the attainment demonstration sections of this SIP submittal are the subject in this rulemaking. The other sections of this SIP submittal will be addressed in a separate rulemaking.

IV. What Is EPA's Review of Pennsylvania's Modeled Attainment Demonstration and Weight of Evidence (WOE) Analysis for the Pennsylvania Portion of the Philadelphia Area?

Section 110(a)(2)(K) of the Clean Air Act requires states to prepare air quality modeling to show how they will meet ambient air quality standards. EPA determined that states must use photochemical grid modeling, or any other analytical method determined by the Administrator to be at least as effective, to demonstrate attainment of the ozone health-based standard in areas classified as 'moderate' or above, and to do so by the required attainment date. *See*, 40 CFR 51.908(c). EPA specified how areas would be classified with regard to the 8-hour ozone standard set by EPA in 1997. *See*, 40 CFR 51.903. EPA followed these procedures and the Philadelphia Area was classified by EPA as being in moderate nonattainment of the 8-hour ozone NAAQS. *See*, 69 FR 23858 (April 30, 2004). The attainment date is June 2010 for moderate areas; therefore, states must achieve emission reductions by the ozone season of 2009 in order for ozone concentrations to be reduced, and attainment achieved during the last complete ozone season before the 2010 deadline.

As more fully described in the TSD, the basic photochemical grid modeling used by Pennsylvania in the Philadelphia Area SIP meets EPA's guidelines, and when used with the methods recommended in EPA's modeling guidance, is acceptable to EPA. EPA's photochemical modeling guidance is found at *Guidance on the Use of Models and Other Analyses for Demonstrating Attainment of Air Quality Goals for Ozone, PM_{2.5}, and Regional Haze*, EPA-454/B-07-002, April 2007. Using EPA's methods, the photochemical grid model, containing the modeled emission reduction strategies prepared by Pennsylvania and the Ozone Transport Commission states, predicts that the 2009 ozone design value in the Philadelphia Area would be

91 parts per billion (ppb). Thus, the photochemical model predicts the Philadelphia Area will not reach the 84 ppb concentration level needed to show attainment of the ozone standard by the 2009 ozone season.

EPA's photochemical modeling guidance is divided into two parts. One part describes how to use a photochemical grid model for ozone to assess whether an area will come into attainment of the air quality standard. The second part of EPA's photochemical modeling guidance strongly recommends that states complement the photochemical air quality modeling with additional analyses (WOE analyses) in situations where modeling predicts the Philadelphia Area to be close to (within several parts per billion of) the ozone standard. A WOE analysis is any set of alternative methods or analyses that, when considered together, and in combination with the modeling analysis, supports the conclusion that the NAAQS has been attained, even in instances when the modeling results alone do not predict attainment. EPA notes in Section 2.3 of its guidance that if the concentration predicted by the photochemical model is 88 ppb or higher, it is "far less likely that the more qualitative arguments made in a weight of evidence determination can be sufficiently convincing to conclude that the NAAQS will be attained."

The Philadelphia Area photochemical grid modeling predicts a 2009 projected design value well above the air quality health standard (91 ppb vs. 84 ppb). As stated above, EPA's photochemical modeling guidance indicates that it is difficult to make a convincing argument to show that ozone will be less than 84 ppb when model predicted concentrations are greater than 88 ppb. As discussed in detail in the TSD at pages 8 through 14, EPA believes that modeling and air quality studies do not support an argument that the attainment will be reached by the June 2010 attainment date.

Additionally, the present air quality (2007 design value 93 ppb, 2008 preliminary design value 92 ppb) also does not support the hypothesis presented in Pennsylvania's WOE analysis that the models are incorrect. Present air quality concentrations should be closer to the standard since the Philadelphia Area is only two years away from its attainment deadline.

The WOE analysis presented in the Pennsylvania SIP revision for the Philadelphia Area includes the following:

- A comparison of predicted 2009 ozone design values and current projected design values for 2006;

- An analysis of recent ozone trends in the Philadelphia Area;
- Alternative methods for calculating the 2009 ozone design value;
- An analysis of model-predicted regional transport; and
- An analysis of model sensitivity to emission changes.

The basic premise of all of the WOE arguments in the Pennsylvania SIP revision for the Philadelphia Area is that the Community Multi-scale Air Quality Model version 4.4 (CMAQ), when applied according to EPA guidance, under-predicts the reduction in ozone that can be expected from the emission control strategies contained in the SIP.

The overarching reason why EPA is not persuaded that the WOE results are robust enough to predict that the Philadelphia Area will attain the standard is that the information and calculations provided in the Pennsylvania SIP revision selectively emphasize methods or data that support the claim that the nonattainment areas could attain the standard by the deadline, while ignoring equally legitimate methods that would tend to support the modeling results, which do not predict attainment. For example, one of Pennsylvania's methods of adjusting the modeled results uses alternative ways of calculating the base air quality value for 2002. The Pennsylvania SIP revision for the Philadelphia Area uses a straight five-year average of the fourth-highest design value from 2000 to 2004. EPA's modeling guidance recommends using an average of the three years of design value centered on 2002, which creates a weighted five-year average. While Pennsylvania's SIP revision notes that EPA's method of providing a weighted average baseline value weights the base year of 2002 more heavily than other years, EPA intended this, so that the resulting value was influenced the most by the ozone data from the base year of the emission inventory. There are other ways of calculating a baseline value that the State did not use. For example, for the peak ozone site of the Philadelphia Area at Colliers Mills:

- The EPA guideline method baseline is 105.7 ppb;
- The Pennsylvania alternative baseline is 104 ppb;
- The 2002 design value is 112 ppb; and
- The 2003 designation design value, centered on 2002, is 105.7 ppb.

Various methods could result in 2002's base year ozone of two ppb lower than the modeling guidance method (Pennsylvania's five year average

centered on 2002) or as much as 7 ppb higher than the guidance method (single design value from 2002). Pennsylvania relies on the lower end of the range of possible results, and this brings the modeling result closer to attainment.

The "sufficiently convincing" WOE analysis our guidance suggests is needed when an area's design value is above 88 ppb, should not be based on a one-sided consideration of only those alternatives that tend to show that an area will attain the ozone standard. To be "sufficiently convincing," the WOE should evaluate other reasonable variations on EPA's methods that reinforce the modeling results that predict the Philadelphia Area will not attain the ozone standard by 2010. Although Pennsylvania has provided a WOE analysis it believes supports its case of attainment in 2010, EPA's evaluation, as set forth at length in the TSD, concludes that the WOE does not demonstrate that the proposed adjustments to the photochemical grid model's attainment year forecast will give a more accurate answer than the calculations based on EPA's recommendations in Sections 2.3 and 7.2 of its modeling guidance.

In general, EPA's conclusions concerning the modeled attainment demonstration and WOE analysis provided in the Pennsylvania SIP revision for the Philadelphia Area can be summarized from the TSD as follows:

- The modeling used in the Philadelphia Area applies an appropriate photochemical grid model and follows EPA's guidance methods, but does not predict attainment in 2010.
- Regardless of the issues raised by Pennsylvania regarding the performance of EPA's recommended air quality models, the air quality measured during 2007 exceeded the ozone standard by a significant margin. Even a linear comparison of the percentage of additional emission reductions planned by the state with the needed improvement in air quality between 2007 and 2009 indicates it is unlikely that air quality will improve enough to meet the ozone standard by June 2010. Preliminary data from the 2008 ozone season also does not support demonstration of attainment by June 2010.
- When comparing the measured ozone concentrations in 2007 and (preliminary) 2008 data to concentrations predicted for 2009, using EPA's recommended application of the photochemical grid modeling, the photochemical grid model does not exhibit the magnitude of inaccuracies suggested in the Pennsylvania SIP revision.

• In order to insure attainment, Pennsylvania suggests that there are additional measures that can achieve emission reductions which were not included in the original photochemical modeling analysis. However, the amount of potential air quality benefit from these measures is difficult to estimate with any degree of certainty. Based on EPA's evaluation of the potential ozone benefits these additional measures may provide for the Philadelphia Area, attainment of the ozone standard in June 2010 cannot be achieved through the adoption of these measures.

- The Philadelphia Area attainment demonstration greatly relied on adjustments to the baseline assumptions which formed the basis of the photochemical modeling analysis. These adjustments to the base year starting value and the amount of reduction in ozone from 2002 to 2009 differ from EPA's modeling guidance, and, more importantly, are not sufficiently justified and are weighted toward a conclusion that Philadelphia Area will attain the standard.

- The Philadelphia Area attainment demonstration greatly relied on research which evaluated the impact of a widespread power blackout to develop an alternative approach to estimating anticipated air quality improvements from upwind power plants. While EPA believes that this approach provides some insight into the transport of ozone precursors, a critical review of all the research available to EPA leads EPA to disagree with Pennsylvania's premise that the 2009 modeled design values should be adjusted downward for alleged model under-predictions of ozone concentration reductions from emission reductions.

A detailed discussion of the EPA's evaluation of the modeled attainment demonstration and WOE analysis contained in the Pennsylvania SIP revision for the Philadelphia Area is located in the TSD entitled, *Technical Support Document for the Modeling and Weight of Evidence Portions of the Commonwealth of Pennsylvania's Ozone State Implementation Plan (SIP) Entitled "Commonwealth of Pennsylvania Department of Environmental Protection State Implementation Plan Revision: Attainment Plan and Base Year Inventory Bucks, Chester, Delaware, Montgomery and Philadelphia Counties located in the Philadelphia-Wilmington-Atlantic City, PA-NJ-DE Eight-Hour Ozone Nonattainment Area, July 2007."*

EPA has carefully evaluated the information provided by Pennsylvania

and other information it deems relevant to help predict what the air quality is likely to be by the 2009 ozone season. After careful consideration of all the relevant information, EPA finds that there is not sufficiently convincing evidence that the Philadelphia Area will attain the 8-hour ozone NAAQS in June 2010. The Pennsylvania SIP revision for the Pennsylvania portion of the Philadelphia Area does not satisfy the Clean Air Act requirement that State Implementation Plans provide for attainment of the NAAQS by the applicable attainment date of June 2010.

V. What Are the Consequences of a Disapproved SIP?

This section explains the consequences of a disapproval of a SIP under the CAA. The CAA provides for the imposition of sanctions and the promulgation of a Federal Implementation Plan if states fail to submit a plan that corrects any deficiencies identified by EPA in its disapproval.

A. What Are the CAA Provisions for Sanctions?

If EPA disapproves a required SIP or component of a SIP for an area designated nonattainment, such as the Attainment Demonstration SIP, section 179(a) provides for the imposition of sanctions unless the deficiency is corrected within 18 months of the final rulemaking of disapproval. The first sanction would apply 18 months after EPA disapproves the SIP if a State fails to make the required submittal which EPA proposes to fully or conditionally approve within that time. Under EPA's sanctions regulations, 40 CFR 52.31, the first sanction would be 2:1 offsets for sources subject to the new source review requirements under section 173 of the CAA. If the State has still failed to submit a SIP for which EPA proposes full or conditional approval 6 months after the first sanction is imposed, the second sanction will apply. The second sanction is a limitation on the receipt of Federal highway funds.

B. What Are the CAA's FIP Ramifications if a State Fails To Submit an Approvable Plan?

In addition to sanctions, if EPA finds that a State failed to submit the required SIP revision or disapproves the required SIP revision, or a portion thereof, EPA must promulgate a FIP no later than 2 years from the date of the finding if the deficiency has not been corrected within that time period.

C. What Are the Ramifications Regarding Conformity?

One consequence of EPA's disapproval of a control strategy SIP is a conformity freeze whereby affected Metropolitan Planning Organizations (MPOs) cannot make new conformity determinations on long range transportation plans and transportation improvement programs (TIPs). If we finalize the disapproval of the attainment demonstration SIP, a conformity freeze will be in place as of the effective date of the disapproval without a protective finding of the budget. See, 40 CFR 93.120(a)(2). This means that no transportation plan, TIP, or project not in the first four years of the currently conforming transportation plan and TIP or that meet the requirements of 40 CFR 93.104(f) during a 12-month lapse grace period² may be found to conform until another attainment demonstration SIP is submitted and the motor vehicle emissions budgets are found adequate or the attainment demonstration is approved. In addition, if the highway funding sanction is implemented, the conformity status of the transportation plan and TIP will lapse on the date of implementation of the highway sanctions. During a conformity lapse, only projects that are exempt from transportation conformity (e.g., road resurfacing, safety projects, reconstruction of bridges without adding travel lanes, bicycle and pedestrian facilities, etc.), transportation control measures that are in the approved SIP and project phases that were approved prior to the start of the lapse can proceed during the lapse. No new project-level approvals or conformity determinations can be made and no new transportation plan or TIP may be found to conform until another attainment demonstration SIP is submitted and the motor vehicle emissions budget is found adequate.

VI. What Is EPA's Conclusion?

EPA is proposing to disapprove the 8-hour ozone attainment demonstration (modeling results and WOE) for the Pennsylvania portion of the Philadelphia Area does not demonstrate with sufficiently convincing evidence that the Philadelphia Area will attain the NAAQS by the June 2010 deadline. EPA is deferring action at this time on other SIP elements submitted by Pennsylvania that are related to the attainment demonstration, specifically,

² Additional information on the implementation of the lapse grace period can be found in the final transportation conformity rule published on January 24, 2008, (73 FR 4423-4425).

the RFP plan, reasonably available control measures analysis, contingency measures, on-road motor vehicle emission budgets, and 2002 base year emissions inventory for the five-county Pennsylvania portion of the Philadelphia Area, which will be addressed in separate rulemakings. The five-county Pennsylvania portion of the Philadelphia Area comprises of Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties. This SIP revision was submitted by the Pennsylvania Department of Environmental Protection on August 29, 2007. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

This action is not a "significant regulatory action" under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, because this proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act will not in-and-of itself create any new information collection burdens but simply disapproves certain State requirements for inclusion into the SIP. Burden is defined at 5 CFR 1320.3(b).

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. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently

owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant impact on a substantial number of small entities. This rule does not impose any requirements or create impacts on small entities. This proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act will not in-and-of itself create any new requirements but simply disapproves certain State requirements for inclusion into the SIP. Accordingly, it affords no opportunity for EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables or exemptions from all or part of the rule. The fact that the Clean Air Act prescribes that various consequences (e.g., higher offset requirements) may or will flow from this disapproval does not mean that EPA either can or must conduct a regulatory flexibility analysis for this action. Therefore, this action will not have a significant economic impact on a substantial number of small entities.

We continue to be interested in the potential impacts of this proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector." EPA has determined that the proposed disapproval action 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 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), 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."

This action does not have federalism implications. It 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 certain State requirements for inclusion into the SIP and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175, Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP EPA is proposing to disapprove would not apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act will not in-and-of itself create any new regulations but simply disapproves certain State requirements for inclusion into the SIP.

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

This action is not subject to Executive Order 13211 (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(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law No. 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through the Office of Management and Budget, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

EPA believes that this action is not subject to requirements of Section 12(d) of NTTAA because application of those requirements would be inconsistent with the Clean Air Act.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this proposed action. In reviewing SIP submissions, EPA's role is to approve or disapprove state choices, based on the criteria of the Clean Air Act. Accordingly, this action merely proposes to disapprove certain State requirements for inclusion into the SIP under section 110 and subchapter I, part D of the Clean Air Act and will not in-and-of itself create any new requirements. Accordingly, it does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898.

In addition, this proposed rule pertaining to the 8-hour ozone attainment demonstration plan of the

five-county Pennsylvania portion of the Philadelphia Area does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Nitrogen dioxide, Ozone, Incorporation by reference, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: April 28, 2009.

William C. Early,

Acting Regional Administrator, Region III.

[FR Doc. E9-10675 Filed 5-7-09; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 50

45 CFR Part 94

[Docket No. NIH-2008-0002]

RIN 0925-AA53

Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Request for Comments

AGENCY: Department of Health and Human Services.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: On behalf of the Department of Health and Human Services (HHS) and the Public Health Service (PHS), a component of the HHS, the National Institutes of Health (NIH) seeks comments from the public on whether the HHS should amend its regulations on the responsibility of applicants for promoting objectivity in research for which PHS funding is sought and on responsible prospective. We are interested particularly in receiving comments on the issues presented below from the general public, individual Investigators, scientific societies and associations, Members of Congress, other Federal agencies that support or conduct research, and institutions that receive PHS funds to conduct or support biomedical or behavioral research.

DATES: To assure consideration, comments must be received by July 7, 2009.

ADDRESSES: Individuals and organizations interested in submitting comments, identified by RIN 0925-AA53 and Docket Number NIH-2008-0002, may do so by any of the following methods:

Electronic Submissions

You may submit electronic comments in the following way:

- *The Regulations.gov portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

To ensure timelier processing of comments, NIH is no longer accepting comments submitted to the agency by e-mail. The NIH encourages you to continue to submit electronic comments by using the Regulations.gov portal: <http://www.regulations.gov>.

Written Submissions

You may send written submissions in the following ways:

- *Fax:* 301-402-0169.
- *Mail: Attention:* Jerry Moore, NIH Regulations Officer, NIH, Office of Management Assessment, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852-7669.
- *Hand Delivery/Courier (for paper, disk, or CD-ROM submissions):* Attention: Jerry Moore, 6011 Executive Boulevard, Suite 601, Rockville, MD 20852-7669.

Docket

For access to the docket to read background documents or comments received, go to the Regulations.gov portal and insert the docket number provided in brackets in the heading on page one of this document into the "Search" box and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Jerry Moore at the address above, or telephone 301-496-4607 (not a toll-free number) concerning questions about the rulemaking process; and Sally J. Rockey, PhD, Deputy Director, Office of Extramural Research, One Center Drive, Building 1, Room 142, Bethesda, MD 20892, e-mail FCOI-ANPRM@NIH.GOV concerning programmatic questions.

SUPPLEMENTARY INFORMATION: Proper stewardship of Federal funds includes ensuring objectivity of results by protecting federally funded research from compromise by financial conflicts of interest (FCOI).

In 1995, the PHS and the Office of the Secretary of Health and Human Services published the regulations at 42 CFR Part 50 Subpart F and 45 CFR Part 94, designed to promote objectivity in PHS-

funded research.¹ The regulations are applicable to Institutions² that apply for PHS funding for research (except for Small Business Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) Phase I applications/proposals) and, through implementation of the regulations by these Institutions, to each Investigator³ participating in the research. Generally, under the regulations:

- The Institution is responsible for complying with the regulations, including developing and maintaining a written and enforced policy; managing, reducing, or eliminating identified conflicts; and reporting identified conflicts to the PHS funding component. The reports denote the existence of a conflict and assure that it has been managed, reduced, or eliminated.

- The participating Investigators are responsible for complying with their Institution's written Financial Conflict of Interest (FCOI) policy and for disclosing their Significant Financial Interests⁴ (SFI) to their Institution.

¹ 48 CFR Subpart 9.1, "Responsible Prospective Contractors," and 48 CFR Subpart 9.5, "Organizational and Consultant Conflicts of Interest," also address conflicts of interest in Federally-funded projects. These provisions apply only to acquisitions, not to grants or cooperative agreements.

² An "Institution" is defined under 42 CFR Part 50, Subpart F, as any domestic or foreign, public or private, entity or organization (excluding a Federal agency), and under 45 CFR Part 94 as any public or private entity or organization (excluding a Federal agency) that (1) submits a proposal for a research contract whether in response to a solicitation from the PHS or otherwise, or (2) that assumes the legal obligation to carry out the research required under the contract. See 42 CFR 50.603; 45 CFR 94.3.

³ An "Investigator" is defined under the regulations as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the regulatory requirements relating to financial interests, the term "Investigator" includes the Investigator's spouse and dependent children. See 42 CFR 50.603; 45 CFR 94.3.

⁴ A "Significant Financial Interest" is defined under the regulation as anything of monetary value, including but not limited to (1) Salary or other payments for services (e.g., consulting fees or honoraria); (2) equity interests (e.g., stocks, stock options or other ownership interests); and (3) intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include (1) Salary, royalties, or other remuneration from the institution; (2) any ownership interests in the institution, if the institution is an applicant under the SBIR program; (3) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; (4) income from service on advisory committees or review panels for public or nonprofit entities; (5) an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership