

determined that the proposed rule, if finalized, would not contain policies that would 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. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

X. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

XI. Reference

FDA has placed the following reference on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday and are available electronically at <http://www.regulations.gov>.

1. Anderson, J. F., "The Influence of Concentration (Gibson's Method) On the Presence of Tetanus Toxin in Blood Serum," *Journal of Experimental Medicine*: 1909 September 2; 11(5): 656–658.

List of Subjects

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 610 and 680 be amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

- 1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.11 [Removed and Reserved]

- 2. Remove and reserve § 610.11.

§ 610.11a [Removed and Reserved]

- 3. Remove and reserve § 610.11a.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

- 4. The authority citation for 21 CFR part 680 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 680.3 [Amended]

- 5. Remove and reserve paragraph (b).

Dated: August 18, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–19888 Filed 8–21–14; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2014–0522; FRL–9915–48–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Infrastructure Requirements for the 2010 Sulfur Dioxide National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia pursuant to the Clean Air Act (CAA). Whenever new or revised National Ambient Air Quality Standards (NAAQS) are promulgated, the CAA requires states to submit a plan for the implementation, maintenance, and enforcement of such NAAQS. The plan is required to address basic program elements including, but not limited to, regulatory structure, monitoring, modeling, legal authority, and adequate resources necessary to assure attainment and maintenance of the standards. These elements are referred to as infrastructure requirements. The Commonwealth of Virginia has made a submittal addressing the infrastructure

requirements for the 2010 sulfur dioxide (SO₂) NAAQS.

DATES: Written comments must be received on or before September 22, 2014.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2014–0522 by one of the following methods:

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

B. *Email:* fernandez.cristina@epa.gov.

C. *Mail:* EPA–R03–OAR–2014–0522, Cristina Fernandez, Associate Director, Office of Air Program Planning, Air Protection Division, Mailcode 3AP30, 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–2014–0522. 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 email. 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 email comment directly to EPA without going through www.regulations.gov, your email 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 Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Ellen Schmitt, (215) 814-5787, or by email at schmitt.ellen@epa.gov.

SUPPLEMENTARY INFORMATION: On June 23, 2014, the Commonwealth of Virginia through the Virginia Department of Environmental Quality (VADEQ) submitted a revision to the Commonwealth's SIP to satisfy the requirements of Section 110(a)(2) of the CAA for the 2010 SO₂ NAAQS.

I. Background

On June 22, 2010, (75 FR 35520), EPA promulgated a revised NAAQS for the 1-hour primary SO₂ at a level of 75 parts per billion (ppb), based on a 3-year average of the annual 99th percentile of 1-hour daily maximum concentrations. Section 110(a) of the CAA requires states to submit SIPs to provide for the implementation, maintenance, and enforcement of a new or revised NAAQS. Specifically, Section 110(a)(1) requires states to submit SIPs meeting the applicable requirements of Section 110(a)(2) within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe, and Section 110(a)(2) requires states to address specific elements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the newly established or revised NAAQS. The contents of a submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains.

II. Summary of SIP Revision

On June 23, 2014, VADEQ provided a SIP revision to satisfy certain Section 110(a)(2) requirements of the CAA for the 2010 SO₂ NAAQS. This revision addressed the following infrastructure elements which EPA is proposing to approve: Section 110(a)(2)(A), (B), (C), (D)(i)(II) (prevention of significant deterioration), (D)(ii), (E)(i), (E)(iii), (F), (G), (H), (J) (consultation, public notification, and prevention of significant deterioration), (K), (L), and (M). A detailed summary of EPA's review and rationale for approving Virginia's submittal may be found in the Technical Support Document (TSD) for this rulemaking action which is available on line at www.regulations.gov, Docket ID Number EPA-R03-OAR-2014-0522.

This rulemaking action does not include any proposed action on Section 110(a)(2)(I) of the CAA which pertains to the nonattainment requirements of part D, Title I of the CAA, because this element is not required to be submitted by the 3-year submission deadline of CAA Section 110(a)(1), and will be addressed in a separate process. This rulemaking action also does not include proposed action on Section 110(a)(2)(D)(i)(I) of the CAA because Virginia's submittal did not include a submittal for this element; therefore, EPA will take later, separate action on Section 110(a)(2)(D)(i)(I) for the 2010 SO₂ NAAQS for Virginia. At this time, EPA is not proposing action on Section 110(a)(2)(D)(i)(II) or (J) for visibility protection for the 2010 SO₂ NAAQS. Although Virginia's infrastructure SIP submittal for the 2010 SO₂ NAAQS referred to Virginia's regional haze SIP for addressing requirements in Section 110(a)(2)(D)(i)(II) and (J) for visibility protection, EPA intends to take separate action on Virginia's submittal for these elements at a later date as explained in the TSD. Finally, EPA will take later, separate action with respect to Section 110(a)(2)(E)(ii) regarding CAA Section 128 requirements for State Boards for the 2010 SO₂ NAAQS. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

III. EPA's Approach To Review Infrastructure SIPs

EPA is acting upon the SIP submission from Virginia that addresses the infrastructure requirements of Section 110(a)(1) and (2) of the CAA for the 2010 SO₂ NAAQS. The requirement for states to make a SIP submission of this type arises out of Section 110(a)(1).

Pursuant to Section 110(a)(1), states must make SIP submissions "within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)," and these SIP submissions are to provide for the "implementation, maintenance, and enforcement" of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that "[e]ach such plan" submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of Section 110(a)(1) and (2) as "infrastructure SIP" submissions. Although the term "infrastructure SIP" does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as "nonattainment SIP" or "attainment plan SIP" submissions to address the nonattainment planning requirements of part D of title I of the CAA, "regional haze SIP" submissions required by EPA rule to address the visibility protection requirements of CAA Section 169A, and nonattainment new source review permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions and Section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in Section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.¹ EPA therefore believes that while the timing requirement in Section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of

¹ For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; Section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and Section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

required elements for infrastructure SIP submissions provided in Section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

The following examples of ambiguities illustrate the need for EPA to interpret some Section 110(a)(1) and Section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is that Section 110(a)(2) requires that “each” SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of title I of the CAA, which specifically address nonattainment SIP requirements.² Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, Section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and Section 107(d)(1)(B) allows up to two years or in some cases three years, for such designations to be promulgated.³ This ambiguity illustrates that rather than apply all the stated requirements of Section 110(a)(2) in a strict literal sense, EPA must determine which provisions of Section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within Section 110(a)(1) and (2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although Section 110(a)(1) directs states to submit “a plan” to meet these requirements, EPA interprets the CAA to allow states to make multiple

SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.⁴ Similarly, EPA interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.⁵

Ambiguities within Section 110(a)(1) and (2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of Section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states’ attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submission for purposes of Section 110(a)(2)(B) could be very different for different pollutants, for example because the content and scope of a state’s infrastructure SIP submission to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.⁶

⁴ See, e.g., “Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting,” 78 FR 4339 (January 22, 2013) (EPA’s final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA’s 2008 PM_{2.5} NSR rule), and “Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 PM_{2.5} NAAQS,” 78 FR 4337 (January 22, 2013) (EPA’s final action on the infrastructure SIP for the 2006 PM_{2.5} NAAQS).

⁵ On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of Sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other Section 110(a)(2) infrastructure SIP elements of Tennessee’s December 14, 2007 submittal.

⁶ For example, implementation of the 1997 PM_{2.5} NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

EPA notes that interpretation of Section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of Section 110(a)(2) that logically apply to these other types of SIP submissions. For example, Section 172(c)(7) requires that attainment plan SIP submissions required by part D have to meet the “applicable requirements” of Section 110(a)(2). Thus, for example, attainment plan SIP submissions must meet the requirements of Section 110(a)(2)(A) regarding enforceable emission limits and control measures and Section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of Section 110(a)(2)(C) that pertains to the prevention of significant deterioration (PSD) program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of Section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of Section 110(a)(1) and Section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of Section 110(a)(1) and Section 110(a)(2) in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in Section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.⁷ EPA most recently

⁷ EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate

² See, e.g., “Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_x SIP Call; Final Rule,” 70 FR 25162, at 25163–65 (May 12, 2005) (explaining relationship between timing requirement of Section 110(a)(2)(D) versus Section 110(a)(2)(I)).

³ EPA notes that this ambiguity within Section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, e.g., that Section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

issued guidance for infrastructure SIPs on September 13, 2013 (2013 Guidance).⁸ EPA developed this document to provide states with up-to-date guidance for infrastructure SIPs for any new or revised NAAQS. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of Section 110(a)(2) that are relevant in the context of infrastructure SIP submissions.⁹ The guidance also discusses the substantively important issues that are germane to certain subsections of Section 110(a)(2). Significantly, EPA interprets Section 110(a)(1) and (2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of Section 110(a)(2), as appropriate.

As an example, Section 110(a)(2)(E)(ii) is a required element of Section 110(a)(2) for infrastructure SIP submissions. Under this element, a state must meet the substantive requirements of Section 128, which pertain to state boards that approve permits or enforcement orders and heads of executive agencies with similar powers. Thus, EPA reviews infrastructure SIP submissions to ensure that the state's SIP appropriately addresses the requirements of Section 110(a)(2)(E)(ii) and Section 128. The 2013 Guidance explains EPA's interpretation that there may be a variety of ways by which states can appropriately address these substantive statutory requirements,

regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

⁸ "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)," Memorandum from Stephen D. Page, September 13, 2013.

⁹ EPA's September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submissions to address Section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the U.S. Supreme Court agreed to review the DC Circuit decision in *EME Homer City*, 696 F.3d 7 (D.C. Cir. 2012) which had interpreted the requirements of Section 110(a)(2)(D)(i)(I). In light of the uncertainty created by ongoing litigation, EPA elected not to provide additional guidance on the requirements of Section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations.

depending on the structure of an individual state's permitting or enforcement program (e.g., whether permits and enforcement orders are approved by a multi-member board or by a head of an executive agency). However they are addressed by the state, the substantive requirements of Section 128 are necessarily included in EPA's evaluation of infrastructure SIP submissions because Section 110(a)(2)(E)(ii) explicitly requires that the state satisfy the provisions of Section 128.

As another example, EPA's review of infrastructure SIP submissions with respect to the PSD program requirements in Section 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements contained in part C and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and NSR pollutants, including Green House Gases (GHGs). By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the 2013 PM_{2.5} NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

For other Section 110(a)(2) elements, however, EPA's review of a state's infrastructure SIP submission focuses on assuring that the state's SIP meets basic structural requirements. For example, Section 110(a)(2)(C) includes, *inter alia*, the requirement that states have a program to regulate minor new sources. Thus, EPA evaluates whether the state has an EPA-approved minor new source review program and whether the program addresses the pollutants relevant to that NAAQS. In the context of acting on an infrastructure SIP submission, however, EPA does not think it is necessary to conduct a review of each and every provision of a state's existing minor source program (*i.e.*, already in the existing SIP) for compliance with the requirements of the CAA and EPA's regulations that pertain to such programs.

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing

provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction that may be contrary to the CAA and EPA's policies addressing such excess emissions (SSM); (ii) existing provisions related to "director's variance" or "director's discretion" that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's "Final NSR Improvement Rule," 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) (NSR Reform). Thus, EPA believes it may approve an infrastructure SIP submission without scrutinizing the totality of the existing SIP for such potentially deficient provisions and may approve the submission even if it is aware of such existing provisions.¹⁰ It is important to note that EPA's approval of a state's infrastructure SIP submission should not be construed as explicit or implicit re-approval of any existing potentially deficient provisions that relate to the three specific issues just described.

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of Section 110(a)(1) and the list of elements in Section 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of "implementation, maintenance, and enforcement" of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a

¹⁰ By contrast, EPA notes that if a state were to include a new provision in an infrastructure SIP submission that contained a legal deficiency, such as a new exemption for excess emissions during SSM events, then EPA would need to evaluate that provision for compliance against the rubric of applicable CAA requirements in the context of the action on the infrastructure SIP.

better approach is for states and EPA to focus attention on those elements of Section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

For example, EPA's 2013 Guidance gives simpler recommendations with respect to carbon monoxide than other NAAQS pollutants to meet the visibility requirements of Section 110(a)(2)(D)(i)(II), because carbon monoxide does not affect visibility. As a result, an infrastructure SIP submission for any future new or revised NAAQS for carbon monoxide need only state this fact in order to address the visibility prong of Section 110(a)(2)(D)(i)(II).

Finally, EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of Section 110(a)(1) and (2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a "SIP call" whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.¹¹ Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.¹² Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in Section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example,

although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that Section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.¹³

IV. Proposed Action

EPA is proposing to approve the following elements of Virginia's June 23, 2014 SIP revision for the 2010 SO₂ NAAQS: Section 110(a)(2)(A), (B), (C), (D)(i)(II) (prevention of significant deterioration), (D)(ii), (E)(i), (E)(iii), (F), (G), (H), (J) (consultation, public notification, and prevention of significant deterioration), (K), (L), and (M). Virginia's SIP revision provides the basic program elements specified in Section 110(a)(2) necessary to implement, maintain, and enforce the 2010 SO₂ NAAQS. This proposed rulemaking action does not include action on Section 110(a)(2)(I) which pertains to the nonattainment planning requirements of part D, Title I of the CAA, because this element is not required to be submitted by the 3-year submission deadline of Section 110(a)(1) of the CAA, and will be addressed in a separate process. Additionally, EPA will take later, separate action on Section 110(a)(2)(D)(i)(I) (interstate transport of emissions), (D)(i)(II) (visibility protection), (J) (visibility protection) and (E)(ii) (Section 128, "State Boards") for the 2010 SO₂ NAAQS as discussed above and in the TSD. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

V. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) "privilege" for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the

privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) Are generated or developed before the commencement of a voluntary environmental assessment; (2) are prepared independently of the assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information "required by law," including documents and information "required by Federal law to maintain program delegation, authorization or approval," since Virginia must "enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. . . ." The opinion concludes that "[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval."

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that "[t]o the extent consistent with requirements imposed by Federal law," any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since "no immunity could be afforded from administrative, civil, or criminal penalties because granting

¹¹ For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See "Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions," 74 FR 21639 (April 18, 2011).

¹² EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. See "Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule," 75 FR 82536 (December 30, 2010). EPA has previously used its authority under CAA Section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, e.g., 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062, November 16, 2004 (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

¹³ See, e.g., EPA's disapproval of a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including Section 110(a)(2)(A). See, e.g., 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4540 (January 26, 2011) (final disapproval of such provisions).

such immunity would not be consistent with Federal law, which is one of the criteria for immunity.”

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, Sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under Section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a “significant regulatory action” subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- 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);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

- 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 (59 FR 7629, February 16, 1994).

In addition, this proposed rule, which satisfies certain infrastructure requirements of Section 110(a)(2) of the CAA for the 2010 SO₂ NAAQS for the Commonwealth of Virginia, 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, Incorporation by reference, Reporting and recordkeeping requirements, Sulfur oxides.

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

Dated: August 5, 2014.

William C. Early,

Acting, Regional Administrator, Region III.

[FR Doc. 2014–20032 Filed 8–21–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2012–0694; FRL–9915–64–Region 4]

Approval and Promulgation of Implementation Plans; South Carolina; Infrastructure Requirements for the 2008 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the July 17, 2012, State Implementation Plan (SIP) submission, provided by the South Carolina Department of Health and Environmental Control (SC DHEC) for inclusion into the South Carolina SIP. This proposal pertains to the Clean

Air Act (CAA or the Act) infrastructure requirements for the 2008 8-hour ozone national ambient air quality standards (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an “infrastructure” SIP. SC DHEC certified that the South Carolina SIP contains provisions that ensure the 2008 8-hour ozone NAAQS is implemented, enforced, and maintained in South Carolina (hereafter referred to as an “infrastructure SIP submission”). With the exception of provisions pertaining to prevention of significant deterioration (PSD) permitting, interstate transport, and visibility protection requirements, EPA is proposing to determine that South Carolina's infrastructure SIP submission, provided to EPA on July 17, 2012, addresses the required infrastructure elements for the 2008 8-hour ozone NAAQS.

DATES: Written comments must be received on or before September 22, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2012–0694, by one of the following methods:

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

2. *Email:* R4-RDS@epa.gov.

3. *Fax:* (404) 562–9019.

4. *Mail:* “EPA–R04–OAR–2012–0694,” Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960.

5. *Hand Delivery or Courier:* Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R04–OAR–2012–0694. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information