

• **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Courtney Buchanan, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2487.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “Supplemental Questions and Answers Regarding Food Facility Registration.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. This draft guidance does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the guidance document entitled “Questions and Answers Regarding Food Facility Registration (Seventh Edition),” to which this draft guidance is a supplement. We intend to finalize this draft guidance document by incorporating the questions and answers into a future edition of the guidance document entitled “Questions and Answers Regarding Food Facility Registration (Seventh Edition).”

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: August 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-17852 Filed 8-17-18; 8:45 am]

BILLING CODE 4164-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2018-0587; FRL-9982-58—Region 9]

Revisions to California State Implementation Plan; South Coast Air Quality Management District, San Joaquin Valley Air Pollution Control District and Yolo-Solano Air Quality Management; Nonattainment New Source Review Requirements for the 2008 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve three state implementation plan (SIP) revisions submitted by the State of California addressing the nonattainment new source review (NSR) requirements for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS). These SIP revisions address the South Coast Air Quality Management District (SCAQMD or District), San Joaquin Valley Air Pollution Control District (SJVAPCD or District) and Yolo-Solano Air Quality Management District (YSAQMD or District) portions of the California SIP. This action is being taken pursuant to the Clean Air Act (CAA or “Act”) and its implementing regulations.

DATES: Any comments must arrive by September 19, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R09-OAR-2018-0587 at <http://www.regulations.gov>, or via email to R9AirPermits@epa.gov. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from [Regulations.gov](https://www.regulations.gov). For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Laura Yannayon, EPA Region 9, (415) 972-3534, yannayon.laura@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, the terms “we,” “us,” and “our” refer to EPA.

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I. Background and Purpose

On March 12, 2008, the EPA promulgated a revised 8-hour ozone NAAQS of 0.075 parts per million (ppm).¹ Upon promulgation of a new or revised NAAQS, the CAA requires the EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient air quality data. The three California air Districts that are subject to this action were designated nonattainment for the 2008 8-hour ozone NAAQS on April 30, 2012, using years 2009–2011 ambient air quality data.² At the time of designation, the SCAQMD was classified as an Extreme ozone nonattainment area for the South Coast Air Basin and a Severe ozone nonattainment area for the Coachella

Valley Air Basin. The SJVAPCD was classified as an Extreme ozone nonattainment area, and the YSAQMD was classified as a Severe ozone nonattainment area.

On March 6, 2015, EPA issued a final rule entitled, “Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements” (SIP Requirements Rule), which establishes the requirements and deadlines that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where ozone concentrations exceed the 2008 8-hour ozone NAAQS.³ Based on the initial nonattainment designations for the 2008 8-hour ozone standard, each District was required to make a SIP revision addressing nonattainment new source review no later than July 20, 2015.⁴ This requirement may be met by submitting a SIP revision consisting of a new or revised NNSR permit program, or an analysis demonstrating that the existing SIP-approved NNSR permit program meets the applicable 2008 ozone requirements and a letter certifying the analysis.

On February 3, 2017, EPA issued a final rule entitled, “Findings of Failure to Submit State Implementation Plan Submittals for the 2008 Ozone National Ambient Air Quality Standards (NAAQS)” (FFS Rule). The rule found that certain state and local air agencies, including the SCAQMD, SJVAPCD and YSAQMD, had failed to submit a SIP revision in a timely manner to satisfy specific New Source Review requirements that apply to nonattainment areas. The rule established certain deadlines for the imposition of sanctions, if a state does not submit a timely SIP revision addressing the requirements for which the finding was made, and for the EPA to promulgate a Federal Implementation Plan (FIP) to address any outstanding SIP requirements.

II. The State’s Submittal

A. What did the State submit?

Table 1 lists the dates the submitted 2008 Ozone Certification letters addressed by this proposal were adopted by each air District and submitted by the California Air Resources Board (CARB), the agency that serves as the governor’s designee for California SIP submittals.

TABLE 1—SUBMITTED CERTIFICATION LETTERS

District	Adoption date	Submittal date
South Coast AQMD	7/7/2017	11/16/17
San Joaquin Valley APCD	4/19/18	6/19/18
Yolo-Solano AQMD	3/14/18	6/19/18

On July 31, 2018, CARB’s November 16, 2017 submittal of SCAQMD’s 2008 Certification letter was deemed to meet the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review. On July 18, 2018, CARB’s June 19, 2018 submittal of SJVAPCD’s and YSAQMD’s 2008 Certification letters were also deemed to meet the completeness criteria in 40 CFR part 51, appendix V.

B. What is the purpose of the submitted certification letters?

The submittal from each District is intended to satisfy the SIP Requirement Rule that requires states to make a SIP revision addressing nonattainment new source review and the FFS Rule that

requires each District to make a SIP submittal by September 6, 2018. The SIP for each District currently contains approved NNSR permit programs based on their nonattainment classification for the 1997 8-hour ozone NAAQS. The submitted certification letters provide a mechanism for each District to satisfy the 40 CFR 51.1114 submittal requirements based on their 2008 8-hr ozone nonattainment designations. EPA’s analysis of how these SIP revisions address the NNSR requirements for the 2008 8-hour ozone NAAQS is provided below.

III. Analysis of Nonattainment New Source Review Requirements

The minimum SIP requirements for NNSR permitting programs for the 2008 8-hour ozone NAAQS are contained in 40 CFR 51.165. These NNSR program requirements include those promulgated in the “Phase 2 Rule” implementing the 1997 8-hour ozone NAAQS⁵ and the SIP Requirements Rule implementing the 2008 8-hour ozone NAAQS. Under the Phase 2 Rule, the SIP for each ozone nonattainment area must contain NNSR provisions that: (1) Set major source thresholds for nitrogen oxides (NO_x) and volatile organic compounds (VOC) pursuant to 40 CFR 51.165(a)(1)(iv)(A)(1)(i)–(iv) and (2); (2) classify physical changes at a major

¹ 73 FR 16436 (March 27, 2008).
² 77 FR 30088 (May 21, 2012).
³ 80 FR 12263 (March 6, 2015). The SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2008 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology, reasonably available control measures, major new source review, emission inventories, and the timing of SIP submissions and of compliance

with emission control measures in the SIP. The rule also revokes the 1997 ozone NAAQS and establishes anti-backsliding requirements.
⁴ 40 CFR 51.1114.
⁵ 70 FR 71612 (November 29, 2005).

source if the change would constitute a major source by itself pursuant to 40 CFR 51.165(a)(1)(iv)(A)(3); (3) consider any significant net emissions increase of NO_x as a significant net emissions increase for ozone pursuant to 40 CFR 51.165(a)(1)(v)(E); (4) consider any increase of VOC emissions in extreme ozone nonattainment areas as significant net emissions increases and major modifications for ozone pursuant to 40 CFR 51.165(a)(1)(v)(F); (5) set significant emissions rates for VOC and NO_x as ozone precursors pursuant to 40 CFR 51.165(a)(1)(x)(A)–(C) and (E); (6) contain provisions for emissions reductions credits pursuant to 40 CFR 51.165(a)(3)(ii)(C)(1)–(2); (7) provide that the requirements applicable to VOC also apply to NO_x pursuant to 40 CFR 51.165(a)(8); and (8) set offset ratios for VOC and NO_x pursuant to 40 CFR 51.165(a)(9)(ii)–(iv). Under the SIP Requirements Rule the SIP for each ozone nonattainment area designated nonattainment for the 2008 8-hour ozone NAAQS and designated nonattainment for the 1997 ozone NAAQS as of April 6, 2015, must also contain NNSR provisions that include the anti-backsliding requirements at 40 CFR 51.1105.

A. South Coast Air Quality Management District (SCAQMD)

The SCAQMD's longstanding SIP-approved NNSR program,⁶ established in Regulation XIII—*New Source Review*, of the SCAQMD's Rules and Regulations, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. The SCAQMD's submitted SIP revision includes a demonstration, consisting of a table listing each of the Phase 2 Rule and SIP Requirements Rule NNSR program requirements and a citation to the specific provision of the rule satisfying the requirement. The submittal also includes a certification by the SCAQMD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designations. These documents are available in the docket for this action. EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the SCAQMD's submittal because the current SIP-approved NSR program contains all the Phase 2 Rule and SIP Requirements Rule NNSR program requirements applicable to the South Coast Air Basin as an Extreme ozone

nonattainment area, and all the requirements applicable to the Coachella Valley Air Basin as a Severe ozone nonattainment area.

B. San Joaquin Valley Air Pollution Control District (SJVAPCD)

The SJVAPCD's longstanding SIP-approved NNSR program,⁷ established in Rule 2201—*New and Modified Stationary Source Review Rule*, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. The SJVAPCD's submitted SIP revision includes a demonstration, consisting of a table listing each of the Phase 2 Rule and SIP Requirements Rule NNSR program requirements and a citation to the specific provision of the rule satisfying the requirement. The submittal also includes a certification by the SJVAPCD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designations. These documents are available in the docket for this action. EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the SJVAPCD's submittal because the current SIP-approved NSR program contains all the Phase 2 Rule and SIP Requirements Rule NNSR program requirements applicable to an Extreme ozone nonattainment area.

C. Yolo-Solano Air Quality Management District (YSAQMD)

The YSAQMD's longstanding SIP-approved NNSR program,⁸ established in Rule 3.4—*New Source Review*, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. The YSAQMD's submitted SIP revision includes a demonstration, consisting of a table listing each of the Phase 2 Rule and SIP Requirements Rule NNSR program requirements and a citation to the specific provision of the rule satisfying the requirement. The submittal also includes a certification by the YSAQMD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designations. These documents are available in the docket for this action. EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the YSAQMD's submittal because the

current SIP-approved NSR program contains all the Phase 2 Rule and SIP Requirements Rule NNSR program requirements for a Severe ozone nonattainment area.

IV. Proposed Action and Public Comment

EPA is proposing to approve SIP revisions addressing the NNSR requirements for the 2008 8-hour ozone NAAQS for the SCAQMD, SJVAPCD and YSAQMD. In support of this proposed action, we have concluded that our approval of the submitted 2008 Ozone certifications for each District would comply with section 110(l) of the Act because the submittals will not interfere with continued attainment of the NAAQS in each District. EPA has concluded that the State's submission fulfills the 40 CFR 51.1114 revision requirement and meets the requirements of CAA section 110 and the minimum SIP requirements of 40 CFR 51.165. The intended effect of our proposed action is to approve the submitted certifications as meeting the applicable Phase 2 Rule requirements. If we finalize this action as proposed, our action would incorporate these certifications into the federally enforceable SIP and be codified through revisions to 40 CFR 52.220 (Identification of plan).

We will accept comments from the public on this proposal until September 19, 2018.

In addition, the FFS Rule issued by EPA on February 3, 2017 started an 18-month sanctions clock and a 24-month Federal Implementation Plan (FIP) clock. See 82 FR 9158. The 18-month sanctions clock was stopped upon receipt of California's SIP revisions and our determination that the submittals were complete. We determined the submittals were complete on July 18, 2018, for the SJVAPCD and YSAQMD, and on July 31, 2018, for the SCAQMD. The 24-month FIP clock will stop upon the effective date of our final approval.

V. Incorporation by Reference

In this document, the EPA is proposing to include in a final EPA rule, regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the certifications listed in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available electronically through www.regulations.gov and in hard copy at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

⁶ 61 FR 64291 (December 4, 1996); 64 FR 13514, (March 19, 1999); 71 FR 35157 (June 19, 2006).

⁷ 79 FR 55637 (September 14, 2014).

⁸ 62 FR 36214 (July 7, 1997).

VI. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act 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 Clean Air Act. 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 action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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 Clean Air Act; 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, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have

tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

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

Dated: August 8, 2018.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2018-17835 Filed 8-17-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2013-0290; FRL-9982-43-OAR]

RIN 2060-AT25

National Emission Standards for Hazardous Air Pollutants for Clay Ceramics Manufacturing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This action proposes amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Clay Ceramics Manufacturing. The proposed amendments are in response to a petition for reconsideration filed by industry stakeholders on the final rule promulgated on October 26, 2015, as well as our review of the 2015 rule with respect to other issues raised by stakeholders. This action proposes to revise the temperature monitoring methodology used to demonstrate continuous compliance with the dioxin/furan (D/F) emissions limit of the final rule. In addition, we are proposing to address concerns raised by industry stakeholders regarding visible emissions (VE) monitoring of tunnel kiln stacks for continuous compliance with particulate matter (PM) and mercury (Hg) emission limitations. This action also proposes to amend the requirements for weekly visual inspections of system ductwork and control device equipment for water curtain spray booths. Lastly, this action proposes to amend the NESHAP to include provisions for emissions averaging and make technical corrections.

DATES:

Comments. Comments must be received on or before October 4, 2018.

Public hearing. If anyone contacts us requesting a public hearing on or before August 27, 2018, we will hold a hearing. Additional information about the hearing, if requested, will be published in a subsequent **Federal Register** document and posted at <https://www.epa.gov/stationary-sources-air-pollution/brick-and-structural-clay-products-national-emission-standards>. See **SUPPLEMENTARY INFORMATION** for information on registering and attending a public hearing.

ADDRESSES:

Comments. Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2013-0290, at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. See **SUPPLEMENTARY INFORMATION** for detail about how the EPA treats submitted comments. *Regulations.gov* is our preferred method of receiving comments. However, the following other submission methods are also accepted:

- **Email:** a-and-r-docket@epa.gov. Include Docket ID No. EPA-HQ-OAR-2013-0290 in the subject line of the message.
- **Fax:** (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2013-0290.
- **Mail:** To ship or send mail via the United States Postal Service, use the following address: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2013-0290, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- **Hand/Courier Delivery:** Use the following Docket Center address if you are using express mail, commercial delivery, hand delivery, or courier: EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. Delivery verification signatures will be available only during regular business hours.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Mr. Brian Storey, Sector Policies and Programs Division (D243-03), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-1103; fax number: (919) 541-4991; and email address: storey.brian@epa.gov.

SUPPLEMENTARY INFORMATION:

Public hearing. Please contact Ms. Aimee St. Clair at (919) 541-1063 or by