

(c) \* \* \*

(2) A request for a hearing under this subpart must be addressed to the FDA Division Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

\* \* \* \* \*

■ 34. Revise § 507.75 to read as follows:

**§ 507.75 Presiding officer for an appeal and for an informal hearing.**

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

■ 35. Amend § 507.85 by revising paragraphs (a) and (b)(1) to read as follows:

**§ 507.85 Reinstatement of a qualified facility exemption that was withdrawn.**

(a) If the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak, the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) will, on his or her own initiative or on the request of a facility, reinstate the exemption.

(b) \* \* \*

(1) Submit a request, in writing, to the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine); and

\* \* \* \* \*

**PART 800—GENERAL**

■ 36. The authority citation for part 800 continues to read as follows:

**Authority:** 5 U.S.C. 551–559; 21 U.S.C. 301–399f.

■ 37. Amend § 800.55 by:

- a. Revising the first sentence of paragraph (c), paragraph (d)(3)(xi), the first sentence of paragraph (e), the second sentence of paragraph (g)(1), and paragraphs (g)(3)(ii) and (iv) and (g)(4);
- b. Adding a heading for paragraph (h); and

■ c. Revising paragraphs (h)(1), (2), and (3) introductory text, (h)(3)(iv), and (h)(4).

The revisions and addition read as follows:

**§ 800.55 Administrative detention.**

\* \* \* \* \*

(c) \* \* \* The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless the FDA Division Director in whose division the devices are located determines that a greater period is required to seize the devices, to institute injunction proceedings, or to evaluate the need for legal action, in which case the Division Director may authorize detention for 10 additional calendar days. \* \* \*

(d) \* \* \*

(3) \* \* \*

(xi) The mailing address, telephone number, and name of the FDA Division Director.

(e) \* \* \* A detention order, before issuance, shall be approved by the FDA Division Director in whose division the devices are located. \* \* \*

(g) \* \* \*

(1) \* \* \* Any appeal shall be submitted in writing to the FDA Division Director in whose division the devices are located within 5 working days of receipt of a detention order.

(3) \* \* \*

(ii) A request for a hearing under this section should be addressed to the FDA Division Director.

\* \* \* \* \*

(iv) Paragraph (g)(4) of this section, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also shall decide the appeal, shall be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director who is permitted by § 16.42(a) of this chapter to preside over the hearing.

\* \* \* \* \*

(h) *Movement of detained devices.* (1) Except as provided in this paragraph (h), no person shall move detained devices within or from the place where they have been ordered detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(2) If detained devices are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put

them in final form. As soon as the devices are moved for the purpose of the preceding sentence, the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible division office official, of the movement of the devices. As soon as the devices are put in final form, they shall be segregated from other devices, and the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible division office official, of their new location. The devices put in final form shall not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible division office official, may approve, in writing, the movement of detained devices for any of the following purposes:

\* \* \* \* \*

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible division office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained devices under paragraph (h)(3) of this section, the detained devices shall remain segregated from other devices and the person responsible for their movement shall immediately orally notify the official who approved the movement of the devices, or another responsible FDA division office official, of the new location of the detained devices.

\* \* \* \* \*

Dated: March 9, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–05213 Filed 3–23–20; 8:45 am]

**BILLING CODE 4164–01–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA–R09–OAR–2019–0432; FRL–10005–66–Region 9]

**Air Plan Approval; California; Santa Barbara County Air Pollution Control District; Stationary Source Permits and Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Santa Barbara

County Air Pollution Control District's (SBAPCD or "the District") portion of the California State Implementation Plan (SIP). These revisions concern the District's New Source Review (NSR) permitting program for new and modified sources of air pollution under section 110(a)(2)(C) of the Clean Air Act (CAA). This action updates the SBAPCD's applicable SIP with current permitting rules.

**DATES:** These rules are effective on April 23, 2020.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-R09-OAR-2019-0432. All documents in the docket are listed on

the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <http://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

**FOR FURTHER INFORMATION CONTACT:** Eugene Chen, EPA Region IX, 75

Hawthorne Street (AIR-3-2), San Francisco, CA 94105. (415) 947-4304, [chen.eugene@epa.gov](mailto:chen.eugene@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document, "we," "us" and "our" refer to the EPA.

**Table of Contents**

- I. Proposed Action
- II. Public Comments and EPA Responses
- III. EPA Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

**I. Proposed Action**

On October 24, 2019 (84 FR 56961), the EPA proposed to approve the following rules into the California SIP.

TABLE 1—SUBMITTED RULES

Rule No.	Rule title	Adopted/ amended date	Submitted date
102 .....	Definitions .....	8/25/2016	10/18/2016
105 .....	Applicability .....	8/25/2016	10/18/2016
202 .....	Exemptions to Rule 201 .....	8/25/2016	10/18/2016
204 .....	Applications .....	8/25/2016	10/18/2016
205 .....	Standards for Granting Permits .....	4/17/1997	3/10/1998
809 .....	Federal Minor Source New Source Review .....	8/25/2016	10/18/2016

Collectively, these submitted rules establish the NSR requirements for minor stationary sources under the SBAPCD's jurisdiction in California. We proposed to approve these rules because we determined they complied with the relevant CAA requirements. Our proposed action contains more information on the submitted rules and our evaluation.

**II. Public Comments and EPA Responses**

The EPA's proposed action provided a 30-day public comment period. We received two comments during this public comment period. Both comments were supportive of the proposed action, and expressed support for further measures to protect air and water quality. The EPA acknowledges the comments and the support expressed by the commenters.

**III. EPA Action**

No comments were submitted that change our assessment of the rules as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving these rules into the California SIP as proposed.

**IV. Incorporation by Reference**

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In

accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Santa Barbara County Air Pollution Control District rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through [www.regulations.gov](http://www.regulations.gov) and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

**V. 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, the 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);

- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- 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 the 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 the 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).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 26, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

**List of Subjects in 40 CFR Part 52**

Air pollution control, Carbon monoxide, Environmental Protection, Incorporation by reference, Intergovernmental relations, Lead, New source review, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Dated: January 24, 2020.

**Deborah Jordan,**

*Acting Regional Administrator, Region IX.*

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

**PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS**

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

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

**Subpart F—California**

- 2. Section 52.220 is amended by adding paragraphs (c)(51)(xiii)(H) and (I), (c)(186)(i)(E)(2), (c)(254)(i)(C)(8) and (9), (c)(423)(i)(E)(6), and (c)(533) to read as follows:

**§ 52.220 Identification of plan—in part.**

\* \* \* \* \*

- (c) \* \* \*
- (51) \* \* \*
- (xiii) \* \* \*

(H) Previously approved on May 5, 1982, in paragraph (c)(51)(xiii)(A) of this section and now deleted with replacement in paragraph (c)(533)(i)(A)(3) of this section, Rule 202, “Exemptions to Rule 201,” revision adopted on August 25, 2016.

(I) Previously approved on May 5, 1982, in paragraph (c)(51)(xiii)(A) of this section and now deleted with replacement in paragraph (c)(254)(i)(C)(8) of this section, Rule 205, “Standards for Granting Permits,” revision adopted April 17, 1997.

\* \* \* \* \*

- (186) \* \* \*
- (i) \* \* \*
- (E) \* \* \*

(2) Previously approved on June 3, 1999, in paragraph (c)(186)(i)(E)(1) of this section and now deleted with replacement in paragraph (c)(533)(i)(A)(2) of this section, Rule 105, “Applicability,” revision adopted on August 25, 2016.

\* \* \* \* \*

- (254) \* \* \*
- (i) \* \* \*
- (C) \* \* \*

(8) Rule 205, “Standards for Granting Permits,” revision adopted April 17, 1997.

(9) Previously approved on February 9, 2016, in paragraph (c)(254)(i)(C)(7) of this section and now deleted with replacement in paragraph (c)(533)(i)(A)(4) of this section, Rule 204, “Applications,” revision adopted on August 25, 2016

\* \* \* \* \*

- (423) \* \* \*

- (j) \* \* \*
- (E) \* \* \*

(6) Previously approved on April 11, 2013, in paragraph (c)(423)(i)(E)(1) of this section and now deleted with replacement in paragraph (c)(533)(i)(A)(1) of this section, Rule 102, “Definitions,” revision adopted on August 25, 2016.

\* \* \* \* \*

(533) New or amended regulations for the following APCD was submitted on October 18, 2016 by the Governor’s designee.

(i) *Incorporation by reference.* (A) Santa Barbara County Air Pollution Control District.

(1) Rule 102, “Definitions,” revision adopted on August 25, 2016.

(2) Rule 105, “Applicability,” revision adopted on August 25, 2016.

(3) Rule 202, “Exemptions to Rule 201,” revision adopted on August 25, 2016.

(4) Rule 204, “Applications,” revision adopted on August 25, 2016.

(5) Rule 809, “Federal Minor Source New Source Review,” revision adopted on August 25, 2016.

- (B) [Reserved]
- (ii) [Reserved]

[FR Doc. 2020–05196 Filed 3–23–20; 8:45 am]

**BILLING CODE 6560–50–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 62**

[EPA–R01–OAR–2020–0083; FRL–10006–58–Region 1]

**Approval and Promulgation of State Plan (Negative Declaration) for Designated Facilities and Pollutants: Vermont**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking a direct final action to approve a negative declaration submitted to satisfy the requirements of the Emission Guidelines and Compliance Times for Municipal Solid Waste Landfills for the State of Vermont. The negative declaration certifies that there are no existing facilities in the State of Vermont that must comply with this rule.

**DATES:** This direct final rule will be effective May 26, 2020 without further notice, unless the EPA receives adverse comments by April 23, 2020. If the EPA receives adverse comments, we will publish a timely withdrawal of the direct final rule in the **Federal Register**