

II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's September 28, 2022, proposed rule on "Protection of Human Subjects and Institutional Review Boards" (87 FR 58733), which this draft guidance is intended to interpret, and with previously approved collections of information described in the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule). The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (87 FR 58733 at 58744) and they have been approved under OMB control number 0910–0130. The collections of information in 45 CFR 46 and the final rule entitled, "Federal Policy for the Protection of Human Subjects" (Common Rule) have been approved under OMB control number 0990–0260.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, <https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-clinical-policy>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <http://www.hhs.gov/ohrp/newsroom/rfc/index.html>, or <https://www.regulations.gov>.

Dated: February 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0626; FRL–11614–03–R9]

Air Plan Disapproval; California; Los Angeles-South Coast Air Basin; 1997 8-Hour Ozone; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for a proposed rule published February 2, 2024. The current comment period for the proposed rule was set to end on March 4, 2024. In response to requests from several commenters, the EPA is extending the comment period for the proposed action to April 3, 2024. **DATES:** The comment period for the proposed rule published on February 2, 2024, at 89 FR 7320 is extended. Comments must be received on or before April 3, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2023–0626 at <https://www.regulations.gov>. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](https://www.regulations.gov). 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 <https://www.epa.gov/dockets/commenting-epa-dockets>. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please

contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3964 or by email at vagenas.ginger@epa.gov.

SUPPLEMENTARY INFORMATION: On February 2, 2024, the EPA published a proposal to disapprove a state implementation plan revision submitted by the State of California to meet Clean Air Act (CAA) requirements for the 1997 8-hour ozone national ambient air quality standards (NAAQS) in the Los Angeles-South Coast Air Basin, California ozone nonattainment area. This submission, titled "Final Contingency Measure Plan—Planning for Attainment of the 1997 80 ppb 8-hour Ozone Standard in the South Coast Air Basin," addresses the CAA requirements for the submission of contingency measures that will be implemented if emissions reductions from anticipated technologies associated with the area's 1997 ozone NAAQS attainment demonstration are not achieved. For more detailed information about this matter, please refer to the February 2, 2024 **Federal Register** document.

The notice of proposed rulemaking initially provided for comments to be submitted to the EPA on or before March 4, 2024 (a 30-day public comment period). The EPA received several comments requesting an extension of the comment period. To ensure the public has sufficient time to evaluate the proposal and develop comments, the EPA is extending the comment period until April 3, 2024.

Dated: February 23, 2024.

Matthew Lakin,

Acting Director, Air and Radiation Division, Region IX.

[FR Doc. 2024–04287 Filed 2–29–24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2023–0617; FRL–11781–01–R3]

Air Plan Approval; Delaware; Amendments to Delaware's Requirements for Public Notice of Certain Permits

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 State of Delaware into Delaware's existing SIP-approved public notice requirements for certain permits authorized under Delaware regulation 1102. The revisions Delaware made to its underlying regulation standardize the public notices requirements across various permits under Delaware regulation 1102 to be consistent with EPA's October 18, 2016 final rule amendments to the notice and comment requirements for Title V, new source review and outer continental shelf (OCS) permit programs. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before April 1, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R03-OAR-2023-0617 at www.regulations.gov, or via email to Opila.Marycate@epa.gov. For comments submitted at Regulations.gov, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. For either manner of submission, 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. 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 www.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT: Yongtian He, Permits Branch (3AD10), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, Four Penn Center, 1600 John F. Kennedy Boulevard, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814-2339. Mr. He can also be reached via electronic mail at He.Yongtian@epa.gov.

SUPPLEMENTARY INFORMATION: On November 10, 2022, the Delaware

Department of Natural Resources and Environmental Control (DNREC) submitted to EPA a revision to the Delaware SIP. DNREC revised 7 DE Admin Code 1102 (DE 1102) to standardize the public notice requirements for certain permits authorized under DE 1102 to be consistent with EPA's final rule entitled, "Revisions to Public Notice Provisions in Clean Air Act Permitting Programs," (81 FR 71613; October 18, 2016) and the implementing regulations codified in 40 CFR 70.7(h)(2).

I. Background

The CAA requires stationary sources of air pollution to obtain permits to construct and operate. EPA's permitting regulations are contained in 40 CFR parts 51, 52, 70, and 71, and cover the requirements for Federal permit actions (*i.e.*, when either EPA or a state or local air agency that has been delegated EPA's authority issues a Federal air permit). These regulations also establish the minimum requirements for EPA approval of state or tribal implementation plans (SIPs) and permitting programs for the issuance of state permits. EPA's regulations contain, among other things, requirements for public notice and availability of supporting information to allow for informed public participation in permit actions (public notice requirements).

On October 18, 2016, EPA issued a final rule (October 18, 2016 rule) that, among other things, revised the public notice requirements for the New Source Review (NSR) construction permits, OCS, and title V operating permits issued by either EPA or by state, local or tribal air agencies exercising Federal authority delegated by the EPA.¹ EPA's October 18, 2016 rule also amended the regulatory requirements for obtaining EPA-approval of state, local, or tribal air permitting programs, but October 18, 2016 rule did not require states to revise their public notice requirements. However, any state that did so would need to revise their requirements consistent with the regulations revised by EPA's October 18, 2016 rule in order to receive EPA approval of those changes.

Delaware amended 7 DE Admin. Code 1102 (DE 1102) to voluntarily update the public notice requirements for permits covered by the regulation to be consistent with certain provisions of the October 18, 2016 rule regulatory revisions. Specifically, Delaware has amended the public notice requirements in DE 1102 to require that each public notice include: (1) The name, address,

and telephone number of a person (or an email or website address) of DNREC Staff from whom interested persons may obtain additional information; and (2) The time and place of any hearing that may be held, including a statement of procedures to request a hearing (unless a hearing has already been scheduled).²

II. Summary of SIP Revision and EPA Analysis

Delaware's November 10, 2022 SIP submission reflects amendments made to its public notice requirements in DE 1102 that are identical to those in the October 18, 2016 rule's public notice requirements. While DE 1102 applies to some permits that are not covered by EPA's October 18, 2016 rule (such as minor sources), some of the permits covered by DE 1102 are also permits addressed by the October 18, 2016 rule, such as major source operating permits (which are covered under DE 1130). The October 18, 2016 rule established requirements for obtaining EPA-approval of state, local, or tribal air permitting programs changes.

Delaware's submittal consists of changes to subsections 12.3.2 and 12.4.2 of DE 1102. As previously mentioned, these subsections have been amended to require that each public notice include: (1) The name, address, and telephone number of a person (or an email or website address) of DNREC Staff from whom interested persons may obtain additional information; and (2) The time and place of any hearing that may be held, including a statement of procedures to request a hearing (unless a hearing has already been scheduled). The updated regulatory language in DE 1102 (and DE 1130) mirrors that of EPA's October 18, 2016 rule and Federal regulations regarding public notice requirements for major source permits (81 FR 71613 and 40 CFR 70.7(h)(2)).

This amendment to DE 1102 is not a required SIP revision, however, having chosen to do so, the changes to DE 1102, to the extent they pertain to permits covered by the October 18, 2016 rule, must meet the requirements of that rulemaking and the affected EPA regulations. EPA has determined that the revisions to DE 1102 meet this requirement, and that this SIP revision

²Delaware had previously revised the public notice operating requirements of its title V operating permit regulations, 7 DE Admin. Code 1130 (DE 1130). DE 1102 also applies to title V sources covered by 1130 as well as other sources, such as minor sources not covered by DE 1130. The effect of these changes is to make all sources covered by DE 1102 and 1130 subject to identical public notice requirements. The changes to DE 1130 have not been submitted to EPA for approval and are not part of this rulemaking.

¹See 81 FR 71613.

is approvable because it is consistent with EPA requirements for major sources as described in EPA's October 18, 2016 rule.³ Additionally, because this SIP revision addresses procedural requirements and not emissions or emissions increases, the submittal is approvable because it will not cause or contribute to a violation of any National Ambient Air Quality Standard (NAAQS), nor will it interfere with any applicable requirement concerning attainment or any other applicable CAA requirement, in accordance with CAA section 110(l).

III. Proposed Action

EPA is proposing to approve the Delaware SIP revision to subsections 12.3.2 and 12.4.2 of 7 DE Admin Code 1102, Permits, which was submitted on November 10, 2022. EPA is soliciting public comments on the proposed rulemaking for the next 30 days. Relevant comments will be considered before taking the final action.

IV. Incorporation by Reference

In this document, 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, EPA is proposing to incorporate by reference the amendments to subsections 12.3.2 and 12.4.2 of DE 1102, as discussed in section I and II of this document. EPA has made, and will continue to make, these materials generally available through www.regulations.gov and at the EPA Region III 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 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 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); and

- 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.

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address "disproportionately high and adverse human health or environmental effects" of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (E.J.) as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies." EPA further defines the term fair treatment to mean that "no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies."

DNREC did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an E.J. analysis and did not consider E.J. in this proposed rulemaking. Due to the nature of the proposed action being taken here, where EPA is approving revisions of the

state regulations to be consistent with notice and comment provisions previously established by EPA, this proposed rulemaking is expected to have a neutral to positive impact on the air quality of the affected area.

In addition, this proposed rule, regarding Delaware's amendments to 7 DE Admin. Code 1102, 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, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Adam Ortiz,

Regional Administrator, Region III.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2023-0458; FRL-11759-01-R4]

Air Plan Approval; Tennessee; Revisions to the Continuous Opacity Monitoring System Requirements

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 State of Tennessee through the Department of Environment and Conservation (TDEC), Division of Air Pollution Control, via a letter dated September 28, 2022. The SIP revision seeks to modify the State's required monitoring standards by adding exemptions to opacity monitoring requirements. EPA is proposing this action pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before April 1, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2023-0458 at regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed

³ See 81 FR 71613.