shall sign a copy of the summary. A copy of the summary must be given to the subject, in addition to a copy of the short form.

§§ 26.1118–26.1122 [Reserved]

§ 26.1123 Early termination of research.

The Administrator may require that any project covered by this subpart be terminated or suspended when the Administrator finds that an IRB, investigator, sponsor, or institution has materially failed to comply with the terms of this subpart.

§ 26.1124 [Reserved]

§ 26.1125 Prior submission of proposed human research for EPA review.

Any person or institution who intends to conduct or sponsor human research covered by § 26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by § 26.1115(a), and the following additional information, to the extent not already included:

(a) A discussion of:

(1) The potential risks to human subjects;

(2) The measures proposed to minimize risks to the human subjects;

(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue;

(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and

(5) The balance of risks and benefits of the proposed research.

(b) All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.

(c) Information about how subjects will be recruited, including any advertisements proposed to be used.

(d) A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.

(e) All correspondence between the IRB and the investigators or sponsors.

(f) Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.

■ 7. Revise § 26.1302 to read as follows:

§ 26.1302 Definitions.

The definitions in § 26.1102 apply to this subpart as well.

[FR Doc. 2018–26228 Filed 12–4–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2017–0094; FRL–9987–49–Region 2]

Approval and Promulgation of Implementation Plans: New York Ozone Section 185

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the State of New York's Low Emissions Vehicle program as an alternative program to fulfill the Clean Air Act Section 185 requirement for the New York portion of the New York-Northern New Jersey-Long Island, NY–NJ–CT nonattainment area for the revoked 1979 1-hour ozone National Ambient Air Quality Standard. Clean Air Act Section 185 requires fees to be paid, per ton of emissions, by major sources located in ozone nonattainment areas classified as Severe or Extreme that have failed to attain the National Ambient Air Quality Standard by the required attainment date. The EPA is proposing to find that New York's Low Emissions Vehicle program is no less stringent than a Clean Air Act Section 185 fee program because the emissions reductions achieved by the Low Emissions Vehicle program are at least equivalent to reductions associated with a 185 fee program.

DATES: Comments must be received on or before January 7, 2019.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R02–OAR–2017–0094 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *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 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, 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: Gavin Lau, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, NY 10007–1866, (212) 637–3708, or by email at *Lau.Gavin@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What Action is the EPA proposing?

The EPA is proposing to approve into the State of New York's State Implementation Plan (SIP) the use of an alternative program to fulfill the requirements of Clean Air Act (CAA) Section 185 for the New York (NY) portion of the New York-Northern New Jersey-Long Island, NY–NJ–CT (NY–NJ–CT) nonattainment area for the 1979 1-hour ozone National Ambient Air Quality Standard (NAAQS). NY's Low Emissions Vehicle program (LEV) was updated and adopted as LEV II in 2000 and further revised in 2002. The LEV II program was fully phased in as of the 2007 vehicle model year and resulted in excess emissions reductions. The EPA is proposing to approve the LEV II program as an equivalent alternative program no less stringent than the program required by CAA Section 185 consistent with the principles of CAA Section 172(e).

II. What is the background for the proposed action?

1979 1-Hour Ozone NAAQS

The 1-hour ozone standard designations were established by the EPA following the CAA Amendments in 1990. Each area of the country that was designated as nonattainment for the 1-hour ozone NAAQS was classified by operation of law as marginal, moderate, serious, severe, or extreme depending on the severity of the area's 1-hour ozone air quality problem.[1] The 1-hour ozone NAAQS was set at 0.12 parts per million (ppm). The NY–NJ–CT area was designated as nonattainment and classified as severe-17 with an attainment date of November 15, 2007. The 1-hour NY–NJ–CT area is composed of: Bergen, Essex, Hudson, Hunterdon,

[1] See Clean Air Act sections 107(d)(C) and 181(a).

Middlesex, Monmouth, Morris, Ocean, Passaic, Somerset, Sussex, and Union Counties in New Jersey; Bronx, Kings, Nassau, New York, Queens, Richmond, Rockland, Suffolk, Westchester, and part of Orange County in New York; and parts of Fairfield and Litchfield Counties in Connecticut.

The EPA revoked the 1-hour ozone standard effective June 15, 2005 (69 FR 23951). The EPA still determines whether an area has attained the 1-hour ozone NAAQS by its applicable deadline if it relates to effectuating anti-backsliding requirements that have been specifically retained.

In a June 18, 2012 rulemaking, the EPA determined that the NY–NJ–CT 1-hour ozone nonattainment area failed to attain the 1-hour ozone NAAQS by its applicable attainment deadline of November 15, 2007, based on complete, quality assured and certified ozone monitoring data for 2005–2007. *See* 77 FR 36163 (June 19, 2012). This determination of failure to attain by the NY–NJ–CT attainment date, triggered the provisions of CAA Section 185. In the determination of failure to attain by the NY–NJ–CT attainment date, the EPA indicated that it would address CAA Section 185 fee programs in a future rulemaking.

In the same June 18, 2012 rulemaking, the EPA determined that the NY–NJ–CT 1-hour ozone nonattainment area attained the 1-hour ozone NAAQS based on complete, quality assured, and certified monitoring data for 2008–2010 (77 FR 36163). Current complete, quality assured, and certified monitoring data for the most recent time period of 2015–2017 continues to show that the NY–NJ–CT area continues to attain the 1-hour ozone NAAQS.

Clean Air Act Section 185

CAA Section 185 fee program requirements apply to ozone nonattainment areas classified as Severe or Extreme that fail to attain by the required attainment date. CAA Section 185 requires each major stationary source of volatile organic compounds (VOC) located in an area that fails to attain by its attainment date to pay a fee to the state, for each calendar year following the attainment year, for each ton it emits in excess of 80 percent of the baseline amount. CAA Section 182(f) extends the application of this provision to major stationary sources of oxides of nitrogen (NO_X). In 1990, the CAA set the fee as $5,000 per ton of VOC and NO_X emitted, which is adjusted for inflation, based on the Consumer Price Index, on an annual basis.

Applicability of CAA Section 185 to the NY–NJ–CT area

As discussed above, the NY–NJ–CT 1-hour ozone nonattainment area failed to attain the 1-hour ozone NAAQS by its attainment date of November 15, 2007 (77 FR 36163). As a result, the requirements of CAA Section 185 are applicable to the area, starting in calendar year 2008. The NY–NJ–CT area was determined to attain the 1-hour ozone NAAQS for 2008–2010 (77 FR 36163).

CAA Section 185 Equivalent Alternative Programs

CAA Section 172(e) provides that when the Administrator relaxes a NAAQS, the EPA must ensure that all areas which have not attained that NAAQS maintain ''controls which are not less stringent than the controls applicable to areas designated nonattainment before such relaxation.'' Although Section 172(e) does not apply directly to supplanting one NAAQS with a stronger standard, the EPA has applied the principles of CAA Section 172(e) following revocation of ozone standards. The EPA interprets the principles of 172(e) as authorizing the Administrator to approve on a case-by-case basis and through rulemaking to accept alternatives to the applicable CAA Section 185 fee programs associated with a revoked ozone NAAQS that are ''not less stringent.'' *See generally* 80 FR 12264, 12306 (March 6, 2015).

The EPA notes that it has previously approved alternative programs as not less stringent than the requirements of CAA Section 185 fee programs, consistent with the principles of CAA Section 172(e). See, *e.g.,* 77 FR 50021 (August 20, 2012) (CAA Section 185 alternative for the San Joaquin Valley Unified Air Pollution Control District); 77 FR 74372 (December 14, 2012) (CAA Section 185 alternative for the South Coast Air Quality Management District); *see also Natural Res. Def. Council* v. *EPA,* 779 F.3d 1119 (9th Cir. 2015) (denying petition to review the approval of alternative programs ''[b]ecause EPA reasonably interpreted CAA § 172(e) to give it authority to approve programs that are alternative to, but not less stringent than, § 185 fee programs, EPA's approval of . . . such an alternative program, after reasoned consideration and notice and comment procedure regarding [the rule's] stringency and approach to fee collecting, was proper.'').

Consistent with the principles of CAA Section 172(e), a state can meet the 1-hour ozone Section 185 obligation through either the fee program prescribed in Section 185 of the CAA or an equivalent alternative program, if the state demonstrates that the alternative is not less stringent than the otherwise applicable Section 185 fee program and the EPA approves such demonstration after notice and comment rulemaking. In this action, the EPA is proposing that the State of New York's Low Emission Vehicle program (LEV II) constitutes an approvable alternative CAA Section 185 fee program and invites public comment on this determination.

III. What did New York submit?

On January 31, 2014, the New York State Department of Environmental Conservation (NYSDEC) submitted a request on behalf of the State of New York to the EPA to determine that the State's LEV II program is an equivalent alternate program to the program required under CAA Section 185. On April 7, 2014, NYSDEC submitted a letter to the EPA which included the State's Environmental Notice Bulletin and public comment received on the State's CAA Section 185 submission to the EPA. NYSDEC's submissions included demonstrations of emissions reductions associated with NY's LEV II program, calculation of reductions needed to fulfill the requirements of CAA Section 185, examples of additional VOC and NO_X control measures, a copy of the public notice, and the supportive comment that was received during the state's public participation process. On October 13, 2016, NYSDEC submitted a letter to the EPA providing additional details clarifying LEV II reductions. On April 3, 2018, NYSDEC submitted additional information to the EPA which included an analysis of actual and allowable emissions for facilities located in the NY portion of the NY–NJ–CT 1-hour ozone nonattainment area to support the use of actual emissions for baseline calculations.

IV. What is New York's alternative to the Clean Air Act Section 185 fee program?

NYSDEC submitted a request to the EPA to determine that its LEV II program is an alternative program which satisfies the requirements of CAA Section 185. The CAA Section 185 fee program requires a fee per ton of VOC and NO_X emissions, in the NY–NJ–CT 1-hour ozone nonattainment area, in excess of 80% the baseline amount. NYSDEC examined actual and allowable emissions from major sources of VOC and NO_X for 2007 and determined that the actual emissions were lower than the allowable emissions. In accordance

with the methodology required under CAA Section 185(b)(2) for computing a baseline amount, NYSDEC then compared the actual 2008 and 2009 emissions of VOC and NO_X for each major source to 80% of its 2007 emissions. For sources that emitted greater than 80% of their emissions for 2007, NYSDEC calculated its corresponding excess emissions for 2008 and 2009. For 2008 and 2009, VOC and NO_X excess emissions for major sources were totaled and daily excess emissions per day were calculated. The amount of emissions from the NY State portion of the NY–NJ–CT area subject to the CAA Section 185 fee program was determined to be for 2008: 2.2 tons per day (tpd) of VOC and 8.7 tpd of NO_X; and for 2009: 1.4 tpd of VOC and 4.5 tpd of NO_X. As an alternative to the CAA Section 185 fee program requirement, NYSDEC requested that the EPA find that its LEV II program provided excess emissions reductions greater than 80% of the 2007 baseline for 2008 and 2009.

New York adopted LEV II new vehicle emission standards, identical to those of California LEV II, in Title 6 of the New York Codes, Rules and Regulations (6 NYCRR) Part 218, ''Emission Standards for Motor Vehicles and Motor Vehicle Engines.'' LEV II exhaust emissions standards were fully phased in by the 2007 model year and provided additional reductions from previous LEV standards. NYSDEC had previously submitted to the EPA a supplemental Reasonable Further Progress Plan (RFP) and 2008 projection year emissions inventory, which included VOC and NO_X projections, as part of the attainment demonstration for the New York State Implementation Plan for ozone. The EPA subsequently approved the RFP and 2008 projection year emissions inventory. See 76 FR 51264 (August 18, 2011). The RFP control measures for the 2008 projection year inventory resulted in surplus reductions of 3.94 tpd of VOC and 81.8 tpd of NO_X. LEV II was part of 2008 projection year surplus and was expected to reduce VOC by 2.5 tons per ozone season day and reduce NO_X by 18.9 tons per ozone season day. New York identified that LEV II could be used for an equivalent alternate program to meet the requirements of CAA Section 185 since the reductions were part of the RFP surplus emissions reductions.

In order to make the LEV II ozone season day reductions representative of an entire year, NYSDEC applied a seasonal adjustment factor based on recommendations from the New York State Department of Transportation (NYSDOT). NYSDEC chose a seasonal adjustment factor that was more conservative than the NYSDOT recommendation for urban areas like the New York City area to assure that sufficient reductions were achieved. In applying a seasonal adjustment factor, LEV II attributable reductions of VOC and NO_X were 2.3 tpd and 17.5 tpd, respectively, for all of 2008. Interpolating between 2008 and 2011 projections included in the RFP yielded seasonally adjusted LEV II attributable reductions of VOC and NO_X of 3.2 tpd and 24.4 tpd, respectively, for all of 2009. Additional details regarding seasonal adjustment of emissions reductions can be found in the Technical Support Document.

New York's LEV II emission standards continue to be in place under 6 NYCRR Part 218 and continue to achieve reductions in VOC and NO_X emissions. EPA performed an analysis to verify that LEV II continued to achieve emissions reduction through 2017. The emissions reductions attributable to LEV II in the NY state portion of the NY–NJ–CT area for 2017 were 1,321 tons of NO_X and 558 tons of VOCs. Details regarding 2017 LEV II emissions reduction can be found in the Technical Support Document.

V. What is the EPA's analysis of the alternative to Clean Air Act Section 185 fee program?

For an alternative to CAA Section 185 fee program to be approvable, a state must provide a demonstration that the proposed alternative program is no less stringent than the application of CAA Section 185. EPA has previously stated that one way to demonstrate this is to show that the alternative program provides equivalent or greater fees and/or emissions reductions directly attributable to the application of CAA Section 185 [2]. The state's demonstration should also not underestimate the expected fees and/or emissions reduction from the CAA Section 185 fee program nor overestimate the expected fees and/or emissions reductions associated with the proposed alternative program. In principle, the alternative program must encourage 1-hour ozone NAAQS nonattainment areas to reach attainment as effectively and expeditiously as a CAA Section 185 program. The EPA has previously approved CAA Section 185 alternative programs for the San Joaquin Valley Unified Air Pollution Control District (77 FR 50021) and the South Coast Air Quality Management District (77 FR 74372) (upheld in *Natural Res. Def. Council* v. *EPA,* 779 F.3d 1119 (9th Cir. 2015)).

The EPA is proposing to determine that NY demonstrated that the emissions reductions from LEV II were at least as significant as those that would have been gained from direct application of CAA Section 185 fees. The surplus RFP LEV II projected emissions reductions for 2008 VOC and NO_X were 2.3 tpd and 17.5 tpd. The 2008 CAA Section 185 emissions reductions targets, calculated as amount in excess of 80% of the 2007 baseline, for VOC and NO_X were 2.2 tpd and 8.7 tpd. LEV II projected emissions reductions for 2009 VOC and NO_X were 3.2 tpd and 24.4 tpd. The 2009 CAA Section 185 emissions reductions targets for VOC and NO_X were 1.4 tpd and 4.5 tpd. For 2008 and 2009, the LEV II emissions reduction were greater than the CAA Section 185 targets for both VOC and NO_X. Table 1 below shows the emissions targets and LEV II emission reductions. Since the amount of LEV II attributable emissions reductions is not less stringent than the emissions in excess of 80% of the 2007 baseline, the alternative program is consistent with the anti-backsliding provisions of CAA Section 172(e). LEV II has continued to achieve emissions reductions through 2017.

[2] The EPA initially explained this position in a January 2010 Guidance document. Memorandum from Stephen D. Page, Director, Office of Air Quality Planning and Standards, to Regional Air Division Directors, ''Guidance on Developing Fee Programs Required by Clean Air Act Section 185 for the 1-hour Ozone NAAQS,'' dated January 5, 2010 (January 2010 guidance). The D.C. Circuit Court of Appeals vacated the January 2010 guidance on procedural grounds, but the Court did not prohibit alternative programs, stating that ''neither the statute nor our case law obviously precludes that alternative.'' *NRDC* v. *EPA,* 643 F.3d 322 (D.C. Cir. July 2011).

TABLE 1

Emission reduction	Emissions reduction (tons per day)	
	NO_X	VOC
2008 CAA Section 185 Target	8.7	2.2
2008 LEV II Projection	17.5	2.3
LEV II emissions reduction greater than 2008 target?	Yes	Yes
2009 CAA Section 185 Target	4.5	1.4
2009 LEV II Projection	24.4	3.2
LEV II emissions reduction greater than 2009 target?	Yes	Yes

LEV II was not included as a control measure relied on in the 1-hour Ozone Attainment SIP, including Rate of Progress and RFP for the NY–NJ–CT 1-hour ozone area (67 FR 5170 (February 4, 2002)). LEV was included in the Ozone Attainment Demonstration SIP, but emissions reductions attributable to the LEV II program were not. Projected emissions reductions by control strategy provided by NYSDEC included specific reductions for each control measure including LEV II. Emissions reductions attributable to LEV II are surplus, were not previously accounted for and do not interfere with other applicable requirements concerning attainment, Rate of Progress, and RFP.

In this action, EPA is proposing that the LEV II program is an acceptable alternative program to the 185 fee program consistent with the anti-backsliding provisions of CAA Section 172(e) because it achieves greater emissions reductions than application of the 185 fee program. The principles of Section 172(e) require controls in nonattainment areas that are not less stringent than those that were applied to an area before EPA revoked the one-hour NAAQS.

VI. What action is EPA taking?

EPA is proposing to approve NY's LEV II program as an alternative program to the requirements of CAA Section 185. The EPA proposes to find the LEV II program achieves sufficient reductions to fulfill the requirements of CAA Section 172(e) and 185 for the NY portion of the NY–NJ–CT 1-hour ozone nonattainment area. The LEV II program will be incorporated into the federally enforceable SIP as an alternative CAA Section 185 program if EPA finalizes this action.

VII. 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);
- 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 (Public Law 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 7, 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 proposed rulemaking action 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 proposed rulemaking action 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, Volatile organic compounds.

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

Dated: November 19, 2018.

Peter D. Lopez,

Regional Administrator, Region 2.

[FR Doc. 2018–26475 Filed 12–4–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2017–0735; FRL–9987–48–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Nonattainment New Source Review Requirements for 2008 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Commonwealth of Pennsylvania's state implementation plan (SIP). The revision is in response to EPA's February 3, 2017 Findings of