FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for wearable vibration devices for orthopedic use. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 888.5895 to subpart E to read as follows:

§ 888.5895 Wearable vibration device for orthopedic use.

(a) *Identification.* A wearable vibration device for orthopedic use is a wearable device that uses mechanical vibrations, targeted to specific regions of the skeleton, to reduce loss of bone strength or bone mineral density.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate the reduction in loss of bone strength or bone mineral density. Testing must evaluate patient risks, including regional pain, dizziness, blurred vision, muscle weakness, difficulty with balance, headache, and nausea. The testing must include a minimum of 1 year of follow-up.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be provided:

(i) Characterization of the designed outputs of the device;

(ii) Demonstration of the reliability and reproducibility of device output; and

(iii) Validation that vibration characteristics received by the patient are within safe physiologic limits.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must be provided to demonstrate the electrical safety, mechanical safety, thermal safety, battery safety, and electromagnetic compatibility of the device.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Human factors or usability evaluation must demonstrate that the user can correctly use the device, based solely on reading the directions for use.

(7) Labeling must include the following:

(i) A summary of the clinical performance testing with the device, including clinical outcomes and observed adverse events;

(ii) Information regarding limitations of the clinical significance of the clinical performance testing;

(iii) Instructions on duration and frequency of use, and when to discontinue use of the device; and

(iv) Instructions for device maintenance, including appropriate cleaning of any reusable components and safe disposal of the device.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22589 Filed 11–4–26; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2026–1684; FRL–13268–02–R9]

Air Plan Revisions; Arizona; Maricopa County Air Quality Department; New Source Review; Emission Reduction Credits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is taking final action to approve a revision to the Maricopa County Air Quality Department (MCAQD or ''Department'') portion of the Arizona State Implementation Plan (SIP). This revision establishes a federally enforceable program allowing for the generation of emission reduction credits (ERCs) by retrofitting or replacing existing on-road vehicles with lower emitting vehicles while meeting other Clean Air Act (CAA or ''Act'') requirements. These ERCs are intended to be used as offsets for major stationary sources under the Department's Nonattainment New Source Review (NNSR) program. The EPA is approving this SIP revision because we find that it meets the applicable CAA requirements.

DATES: This rule is effective December 7, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2026–1684. All documents in the docket are listed on the *https://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 *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. 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: Elijah Gordon, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; telephone number: (415) 972–3158; email address: *gordon.elijah@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this final rule, the use of ''we,'' ''us,'' or ''our'' is intended to refer to the EPA. We use multiple abbreviations and terms in this final rule. While this list may not be exhaustive, for ease of reading and for reference purposes, the EPA defines the following terms and acronyms here:

ADEQ—Arizona Department of Environmental Quality
CAA—Clean Air Act
CBI—Confidential Business Information
CFR—Code of Federal Regulations
CNG—compressed natural gas
EIP—economic incentive program
EPA—Environmental Protection Agency
ERC—emission reduction credit
FR—Federal Register
IBR—incorporation by reference
MAG—Maricopa Association of Governments
MCAQD—Maricopa County Air Quality Department
MERC—mobile source emission reduction credit
MOVES—MOtor Vehicle Emission Simulator
NAA—nonattainment area
NAAQS—national ambient air quality standards
NERC—nonroad engine emission reduction credit
NNSR—Nonattainment New Source Review
NO_X—oxides of nitrogen
NSR—New Source Review
PM_{10}—particulate matter 10 micrometers or smaller in diameter
SIP—State Implementation Plan
TPY—tons per year
TSD—technical support document
VOC—volatile organic compounds
U.S.C.—United States Code

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I. Executive Summary

A. What action is the EPA taking?

The EPA is fully approving the Arizona Department of Environmental Quality's (ADEQ's) May 30, 2025, SIP revision for MCAQD Rule 205, ''Emission Offsets Generated by Voluntary Mobile Source Emission Reductions,'' revised on May 21, 2025 (''Rule 205'' or ''MCAQD Rule 205 submittal''). Specifically, the EPA is approving the MCAQD Rule 205 submittal by adding Rule 205 into the federally enforceable portion of the Maricopa County portion of the Arizona SIP.[1] Rule 205 allows for the generation of ERCs through voluntary on-road mobile source emissions reductions. ERCs generated by this rule are intended to be used to offset emissions increases of oxides of nitrogen (NO_X) and volatile organic compounds (VOC) at major stationary sources as part of the preconstruction permit process required by the CAA's NNSR program.

B. What is the legal authority and what are the requirements?

We are taking this action under CAA section 110. Pursuant to CAA section 110(a), States are required to submit SIPs to the EPA that provide for the implementation, maintenance, and enforcement of the national ambient air quality standards (NAAQS). CAA section 110(k) requires SIPs to meet certain procedural requirements and requires the EPA to approve or disapprove SIP submissions. CAA section 110(l) requires States to provide public notice and an opportunity for public hearing of SIP revisions prior to their submittal and prohibits the EPA from approving any SIP revisions that would interfere with attainment or maintenance of a NAAQS, reasonable further progress, or other CAA applicable requirements. If a SIP submittal meets all the applicable CAA requirements, then the EPA must approve the submittal under CAA section 110(k)(3).

In evaluating the MCAQD Rule 205 submittal, the EPA considered whether ERCs generated under the rule would meet the statutory and regulatory requirements for offsetting emissions reductions in CAA section 173 and 40 CFR 51.165, respectively. Emissions reductions may generally be credited for NNSR offset purposes under the CAA if they achieve actual emission reductions in the relevant nonattainment area that (1) are not otherwise required by the CAA or relied upon in any air quality-related programs under the CAA; (2) can be reliably quantified using methods that can be replicated; (3) will continue for the duration of the SIP or other program that relies upon the emission reductions; and (4) are enforceable by the EPA under the CAA.

II. Background

The MCAQD is the local air pollution control agency for Maricopa County, Arizona and is responsible for regulating stationary sources of air pollution within its boundaries. Portions of Maricopa County designated nonattainment for the 2008 and 2015 ozone NAAQS are classified as ''Moderate'' and portions of Maricopa County designated nonattainment for the 1987 particulate matter 10 micrometers or smaller in diameter (PM_{10}) NAAQS are classified as ''Serious.'' [2] In these nonattainment areas, the MCAQD is required to implement an NNSR permit program for preconstruction review of new or modified major stationary sources.[3] One of the requirements of the NNSR program is to provide surplus emissions reductions to offset a proposed project's projected emissions increases.[4]

The MCAQD has stated that the quantity of surplus emissions reductions currently available for use as NNSR offsets do not appear sufficient to support current and projected economic growth. To incentivize the generation of additional offsets, the MCAQD developed Rule 205 to create a regulatory structure for the generation and use of NO_X and VOC ERCs from a nontraditional category. Rule 205 can be used to generate NO_X and VOC ERCs from on-road mobile sources, or mobile source ERCs (MERCs). The rule allows

[1] MCAQD developed an economic incentive program (EIP) support document that is included in Appendix 18 of the MCAQD Rule 205 submittal. The EPA's approval of Rule 205 is based, in part, on the Department's representations in this document of the actions it intends to take to implement Rule 205 and ensure MERCs are consistent with applicable CAA requirements. Therefore, the MCAQD's EIP support document is also being added to the non-regulatory portion of the Arizona SIP.

[2] 40 CFR 81.303.

[3] The major source threshold for both VOC and NO_X, which are precursors of ozone, is 100 tons per year (tpy) for the portions of Maricopa County designated as Moderate nonattainment for the 2008 and 2015 ozone NAAQS. The major source threshold for Serious PM_{10} nonattainment areas is 70 tpy for PM_{10} and precursors to PM_{10}. *See* 40 CFR 51.165(a)(1)(iv). Modifications to existing major sources trigger NNSR review at different thresholds specified in 40 CFR 51.165(a)(1)(x).

[4] 40 CFR 51.165(a)(9)(ii). The required offset ratio for Moderate ozone nonattainment areas is at least 1.15 to 1. The offset ratio for Serious PM_{10} nonattainment areas is at least 1 to 1.

on-road mobile source fleet owners/operators that permanently reduce NO_X or VOC emissions from their fleets, or credit ''generators,'' to trade those reductions with stationary sources, or ''credit users,'' who can then use them to offset their proposed NO_X or VOC emissions increases for the purpose of meeting NNSR permit requirements.

On April 16, 2026, the EPA proposed approving the MCAQD Rule 205 submittal because we determined that this SIP revision complied with all relevant CAA requirements.[5] Table 1 lists the materials we are incorporating into the Arizona SIP. The proposed action and technical support document (TSD) contain more information on the submittal and our evaluation.

TABLE 1—MATERIALS FOR INCLUSION INTO THE ARIZONA SIP

Local agency	Title	Revised	Submitted
MCAQD	Rule 205—Emission Offsets Generated by Voluntary Mobile Source Emission Reductions.	05/21/25	05/30/25
MCAQD	Revision to Arizona's State Implementation Plan (SIP) Addition of Rule 205 to the Maricopa County Air Pollution Control Regulations (MCAPCR), Appendix 18—Economic Incentive Program Support Document.	05/21/25	05/30/25

III. Public Comments and EPA Responses

The EPA provided a 30-day public comment period on our proposed action. The comment period opened on April 16, 2026, the date of publication in the **Federal Register**, and closed on May 18, 2026.[6] During this period, the EPA received comments from five separate commenters. All comments submitted during the public comment period can be found in the docket of this rulemaking.[7]

Four commenters were supportive of the EPA's proposed action.[8] In addition to support for the proposed action, two of these commenters included additional recommendations for the EPA to consider. One commenter recommended that the EPA: (1) clarify that ''future MCAQD revisions incorporating technology-neutral language for software/operational reductions'' would be approvable if the offset integrity criteria are satisfied and (2) commit to updating EPA's Economic Incentive Program (EIP) guidance to clarify that ''software-driven mobile source reductions can qualify for MERCs/NNSR offsets when properly documented and enforced.'' Another commenter encouraged the EPA to continue to take actions that will encourage the generation of ERCs, improve the efficiency of the ERC certification process, and focus on practical actions that could meaningfully improve public health and reduce air pollution. These recommendations from commenters are outside the scope of our final action on the Department's submittal.

One commenter opposed the EPA's proposed action and requested that the EPA disapprove Rule 205. Below, we summarize the commenter's concerns and provide a response to each.

Comment 1: The commenter asserted that the CAA ''does not authorize stationary sources to trade credits with mobile sources because such reductions are not 'permanent, quantifiable, and enforceable' as [CAA section] 173(c)(1) requires.'' Additionally, the commenter stated Congress separated the authority to regulate stationary sources and mobile sources with no references to linking together with respect to generating offsets.

Response 1: The EPA disagrees with the commenter's claim that mobile source emissions reductions cannot be used as offsets for stationary sources under CAA section 173(c)(1). CAA section 173(a) conditions the issuance of an NNSR permit on a determination by the permitting agency that, among other things, sufficient offsetting emissions reductions will be obtained before the new or modified source commences operation so as to represent ''reasonable further progress'' toward attainment of the NAAQS.[9] The required offsetting emissions reductions must be in effect and enforceable by the time the new or modified source commences operations and must assure that the total tonnage of increased emissions of the relevant air pollutant from the source is offset by an equal or greater reduction, as applicable, in the actual emissions of that air pollutant in the area.[10] Under CAA section 173(c)(1), ERCs must be obtained from the same source or other sources in the same nonattainment area, except that the reductions may be obtained from another nonattainment area if two conditions are met: (1) the other area has an equal or higher nonattainment classification than the area where the source is located, and (2) emissions from such other area contribute to a violation of the NAAQS in the nonattainment area where the source is located.[11] These restrictions are designed to ensure that offsets result in the improvement of air quality in the nonattainment area, such that construction (or modification) of the source is consistent with reasonable further progress toward attainment.[12]

Consistent with these statutory requirements, the EPA's NNSR implementing regulations require that all emissions reductions claimed as offset credit be ''federally enforceable'' and that offsetting emissions reductions be obtained from the same source or other sources in the same nonattainment area, except that the reductions may be obtained from another nonattainment area if the two conditions specified in CAA section 173(c)(1) are met.[13] Additionally, the EPA's NNSR regulations provide that emissions reductions achieved by shutting down an existing emission unit or curtailing production or operating hours may be credited for offsets only if, among other things, the reductions are surplus, permanent, quantifiable, and federally

[5] 91 FR 20394 (Apr. 16, 2026).

[6] 91 FR 20394 (Apr. 16, 2026).

[7] *See* Docket No. EPA–R09–OAR–2026–1684 for all comments submitted during the public comment period.

[8] One of the supportive commenters also sent an email, with an attachment, during the comment period that was supportive of the proposed action. The email and attachment are included in the docket for this action.

[9] CAA section 173(a)(1).

[10] CAA section 173(c)(1).

[11] *Id.*

[12] *See* CAA sections 173(a)(1)(A) and 173(c); *see also NRDC* v. *EPA,* 571 F.3d 1245,1267 (D.C. Cir. 2009) (noting ''CAA section 173's mandate that total reductions 'represent . . . reasonable further progress' '').

[13] 40 CFR 51.165(a)(3)(ii)(E) (requiring that all emission reductions claimed as offset credit be federally enforceable) and (F) (requiring States to follow procedures relating to the permissible location of offsetting emissions at least as stringent as those set out in 40 CFR part 51, Appendix S, section IV.D).

enforceable.[14] The EPA has referred to these four creditability criteria in longstanding guidance as ''integrity elements''—*i.e.,* elements of a program that ensure it has integrity and meets applicable statutory requirements.[15] The EPA sometimes refers to these integrity elements, along with the requirement in CAA section 173(c)(1) that offsets be based on the reduction of ''actual'' emissions of the relevant pollutant, as the offset ''integrity criteria.'' [16]

To the extent the commenter intended to assert that stationary sources are regulated under title I of the CAA while mobile sources are regulated under title II of the CAA, this is generally correct. But nothing in CAA section 173 or any other provision of the CAA prohibits the use of emissions reductions from mobile sources within the relevant nonattainment area for NNSR offset purposes, provided the applicable statutory and regulatory requirements are met. The commenter fails to identify any such prohibition in the text of the CAA or the EPA's implementing regulations. The commenter also fails to support its claim that mobile source emissions reductions would not meet the permanent, quantifiable, and federally enforceable offset integrity criteria.[17] The EPA's proposed rule and TSD explained in detail how Rule 205 meets the applicable CAA requirements and addresses the EPA's longstanding integrity criteria for offsetting emissions reductions. In the next few paragraphs, we briefly summarize our prior analysis of the permanent, quantifiable, and federally enforceable criteria.

To ensure emissions reductions from mobile sources meet the permanent criterion, generators of MERCs must demonstrate that replaced vehicles no longer operate in the nonattainment area (NAA) and/or that emissions do not shift to higher emitting vehicles within the fleet. Generators of MERCs do so through enforceable requirements, including robust monitoring, recordkeeping, and reporting requirements. Rule 205 contains several enforceable conditions to ensure that emissions reductions are permanent, including: limiting the applicability of the rule to ''captive fleet'' [18] vehicles; requiring the original baseline vehicle to be permanently removed from the Maricopa NAA or rendered permanently disabled and disposed of; [19] requiring any future replacement of the new or retrofitted fleet vehicle to be with a vehicle that is certified to the same or lower emission standard; [20] and related monitoring, recordkeeping, and reporting requirements.[21] [22]

To ensure emissions reductions from mobile sources meet the quantifiable criterion, generators of MERCs calculate emissions reductions using specific methodologies that are clear and replicable. Appendix A of Rule 205 articulates the calculation formula that MERC generators will use to determine the number of eligible MERCs.[23] Rule 205 requires MERC generators to submit information, within their MERC application, on the methodology for quantifying emissions reductions, including emissions calculations and documentation of each original vehicle's historic vehicle miles traveled.[24] [25] Rule 205 also requires MERC generators to demonstrate that the captive fleet of vehicles used to generate MERCs are based and operated within the NAA.[26] Finally, Rule 205 requires the MCAQD to evaluate whether the proposed qualifying emission reductions within the application for MERCs will result in quantifiable emission reductions.[27] [28]

To meet the requirement in 40 CFR 51.165(a)(3)(ii)(E) that offsetting emissions reductions be federally enforceable, emissions reductions must be enforceable by the EPA and must be legally and practicably enforceable. The term ''federally enforceable'' is defined in the EPA's regulations at 40 CFR 51.165(a)(1)(xiv) to mean ''all limitations and conditions which are enforceable by the Administrator,'' including those requirements developed pursuant to 40 CFR parts 60 and 61, requirements within any applicable SIP, and any permit requirements established pursuant to 40 CFR 52.21 or under regulations approved pursuant to 40 CFR part 51, subpart I. Additionally, reductions are legally and practicably enforceable if the reductions can be independently verified; violations of the program that generated the credits are defined and those liable for the violations can be identified; access to the emissions-related information underlying the credits is available; and the public can file civil lawsuits to enforce violations.[29] The EPA's approval of Rule 205 into the SIP ensures that MERCs issued under the rule are federally enforceable. In addition, after determining that the requested reductions meet the certification criteria, the permits that MCAQD issues pursuant to its SIP-approved NNSR program incorporate requirements that make the reductions in qualifying emissions federally enforceable.[30] [31]

Based on our evaluation, we find that Rule 205 ensures that offsetting emissions reductions will be permanent, quantifiable, and federally enforceable consistent with the requirements of CAA section 173 and 40 CFR 51.165.

Comment 2: The commenter stated that Rule 205 measures emissions reductions solely at the tailpipe, relies on the EPA's MOtor Vehicle Emission Simulator (MOVES) based emission factors, and excludes ''upstream NO_X and VOC emissions associated with electricity generation and transmission needed to power replacement battery electric vehicles.'' Therefore, the commenter believes these actions can, in effect, overstate actual emissions reductions. Because CAA section 173(c)(1) requires emissions increases to be offset by the ''actual emissions'' of such air pollutant within the nonattainment area, the commenter requested the EPA account for upstream

[14] 40 CFR 51.165(a)(3)(ii)(C); 40 CFR part 51, Appendix S, paragraph IV.C.3.

[15] *See* Improving Air Quality with Economic Incentive Programs, EPA–452/R–01–001 (EPA Office of Air and Radiation, 2001) (''EIP Guidance''), available at *https://www.epa.gov/sites/production/files/2015-07/documents/eipfin.pdf*), chapter 4 (describing ''fundamental principles'' of all emission reduction banking and trading programs). The EIP Guidance supersedes the EPA's 1986 *emission trading policy statement* at 51 FR 43813 (Dec. 4, 1986).

[16] *See, e.g.,* 91 FR 20394, 20396 (Apr. 16, 2026).

[17] The commenter did not raise the surplus criterion in the offset integrity criteria in this comment.

[18] Rule 205, section 203 defines captive fleet as, ''[A] fleet of vehicles where all the vehicles in the fleet are identifiable, the locations where they are being operated can be tracked and recorded using a fleet management system, such as a global positioning system (GPS), their base of operation is in a nonattainment area, and which can serve as a permanent source of emission reductions when a vehicle is replaced or retrofitted. The captive fleet can only include on-road vehicles.''

[19] Rule 205, section 302.2c.

[20] Rule 205, section 302.2d.

[21] *See,* for example: Rule 205, sections 302.2, 401.2, 401.3, 501, 503, 504, and 505.

[22] For a fuller discussion on each of these requirements and how they fulfill the permanent criterion, please see pages 16 through 22 of the TSD for this action.

[23] Additionally, section 302.1d of Rule 205 allows MERC generators to use an alternative method to quantify emissions reductions, which must go through the public participation process and receive approval from the Department and the EPA Administrator prior to use.

[24] Rule 205, section 301.1a.(4).

[25] *See* Rule 205, section 209. The original vehicle's historic vehicle miles traveled is based on original vehicle's *actual* vehicle miles traveled within the NAA.

[26] Rule 205, section 302.1a.

[27] Rule 205, section 301.2.

[28] For a fuller discussion on each of these requirements and how they fulfill the quantifiable criterion, please see pages 14 through 16 of the TSD for this action.

[29] *See* EIP Guidance, pages 35 through 36.

[30] Rule 205, sections 301.2 and 301.3b.

[31] For a fuller discussion on each of these requirements and how they fulfill the federally enforceable criterion, please see pages 22 through 23 of the TSD for this action.

''lifecycle'' emissions increases associated with charging electric vehicles by ''requiring MCAQD to include, at minimum, a qualitative disclosure in each MERC application identifying the electricity source and associated upstream NO_X and VOC emissions.''

Response 2: The EPA disagrees with the claim that to approve Rule 205 the EPA must account for upstream ''lifecycle'' emissions potentially associated with charging electric vehicles by requiring the MCAQD to include a qualitative disclosure in each MERC application identifying the electricity source and upstream NO_X and VOC emissions. As an initial matter, we note that Rule 205 is designed to be broadly applicable, and MERCs can be generated using any fuel type (*e.g.,* replacing a diesel engine with a lower-emitting diesel engine). That is, Rule 205 is fuel neutral and not every MERC application will be for electric vehicles, as suggested by the comment.

The commenter's concern that the use of MOVES can overstate the actual emissions reductions eligible for offsets when a vehicle is replaced with an electric vehicle raises a hypothetical, fact-specific issue that is best evaluated in the context of an individual MERC application. The commenter specifically cited to the requirement in CAA section 173(c)(1) that requires emissions increases to ''be offset by an equal or greater reduction, as applicable, in the actual emissions of such air pollutant from the same or other sources in the area.'' As we explained in our proposal, this means the emissions reductions must be ''real'' and not a theoretical reduction in the source's potential to emit; in other words, it requires that each offset represents emissions that have been taken out of the air.[32] The requirements of Rule 205 ensure that this requirement will be met. For example, before granting MERCs, Rule 205 requires the MCAQD to evaluate whether the emissions reductions will be real and include an opportunity for public comment on the Department's evaluation.[33] The rule also defines ''real'' as ''[a] reduction in actual emissions previously released into the air resulting from a physical change or change to the method of operation by a generator.'' [34] Thus, no revisions to Rule 205 are needed to ensure CAA section 173(c)(1) will be met. While the MERC calculation methodology in Appendix A of Rule 205 is meant to be applicable to most situations, if the MCAQD determines that not all of the emissions reductions for a specific project would be real, then the MERC generator could potentially obtain approval from the MCAQD and the EPA for an alternative MERC calculation method.[35] Regardless of the calculation method used, the Department must determine that the requested MERCs will result in real, quantifiable, federally enforceable, permanent, and surplus emissions reductions prior to the MERC generator requesting a permit or permit revision to impose conditions to make the emissions reductions permanent and enforceable.[36]

Comment 3: The commenter stated that Appendix A of Rule 205, which contains the equation used to quantify the number of MERCs, and the MCAQD's EIP support document effectively only addresses electric vehicles. The MOVES model does not ''separately represent hybrid, plug-in hybrid, CNG [compressed natural gas], LNG [liquefied natural gas], or other alternative-fuel vehicles as distinct source types'' and, as a result, non-electric vehicle projects may rely on default MOVES assumptions that do not reflect actual emissions and undermine the ''quantifiability and integrity of generated MERCs.''

Response 3: The EPA disagrees with the commenter's claim that the quantification method in Rule 205 can only be used to generate MERCs through replacing vehicles with electric vehicles. In 2025, MCAQD revised the quantification method in Rule 205 to ensure the rule is fuel neutral. Owners/operators of vehicle fleets can opt to choose any available vehicle type as a replacement as long as it would emit less NO_X and VOC, including diesel, compressed natural gas, gasoline/diesel hybrids, plug-in hybrids, and electric vehicles.

The emission rates within MOVES differ by the vehicle type and by the fuel type used, as well as other aspects of vehicles and their activity.[37] [38] Rule 205 identifies fuel type as one of the data points required to run MOVES.[39] Therefore, the necessary inputs to quantify MERCs are well defined in Rule 205, ensuring emissions from all fuel types are quantifiable under Rule 205.[40] [41]

Comment 4: The commenter stated that the surplus requirement mandates that credited reductions must not otherwise be required by the CAA and, therefore, MERCs must account for tightening Federal vehicle standards. The commenter stated that as EPA emissions standards progressively reduce NO_X and non-methane organic gas emissions, ''the emissions factors embedded in MOVES will increasingly reflect reductions mandated by [F]ederal law,'' which would not qualify as voluntary or surplus reductions. Essentially, ''[r]ule 205 addresses surplus only at the point of application and fails to ensure that credits remain 'surplus' as [F]ederal vehicle standards tighten.''

Response 4: We disagree with the commenter's claim that Rule 205 fails to ensure that MERCs remain surplus as Federal vehicle standards tighten. While not specifically stated in the comment, we assume the commenter is referring to the concept of ''fleet turnover,'' where the totality of the vehicles in an area will emit less air pollutants over time because of the natural cycle of vehicle owners replacing their vehicles with newer models, which are typically subject to more stringent vehicle emissions standards. Because CAA section 173(c)(2) expressly states that ''[e]mission reductions otherwise required by [the CAA] shall not be creditable as emissions reductions for purposes of any such offset requirement,'' emissions reductions used to demonstrate attainment of the NAAQS or to meet transportation conformity requirements would not be creditable for NNSR offset purposes under CAA section 173.

To ensure MERCs are surplus and meet the requirements of CAA section 173(c)(2), the MCAQD Rule 205

[32] 91 FR 20394 (Apr. 16, 2026).

[33] Rule 205, section 301.2 and 301.3a.

[34] Rule 205, section 220.

[35] Rule 205, section 302.1d.

[36] Rule 205, section 301.2.

[37] MOVES categorizes vehicles into 13 source types based on physical characteristics. The source types are based on the Highway Performance Monitoring System (HPMS) vehicle groups. HPMS is defined at 23 CFR 490.101, and includes Motorcycles, Light Duty Vehicles—Short and Long Wheelbase, Buses, Single Unit Trucks, and Combination Trucks. The source types are set based on physical characteristics, such as number of wheels, number of axles, bus, truck type, etc.

[38] MOVES has four tables—FuelSupply, FuelFormulation, FuelUsageFraction, and AVFT (Alternative Vehicle Fuel and Technologies)—that defines the fuels used in the area being modeled. These tables can be adjusted to accurately model the type of fuel being used at the local level.

[39] *See* Appendix A, section A.3.(a) and Appendix A, section B.3.(a) of Rule 205.

[40] *See* EPA's *MOVES5 Technical Guidance: Using MOVES to Prepare Emission Inventories for State Implementation Plans and Transportation Conformity* (EPA–420–B–24–043, Nov. 2024) for further information on how to run and implement these tools within MOVES. The EPA encourages MOVES users to contact us about the application of this guidance to specific SIPs or a regional conformity analysis.

[41] As explained previously, to the extent Rule 205 does not address every possible scenario that may be encountered, generators may obtain approval from the MCAQD and the EPA for an alternative calculation methodology as prescribed in Section 302.1d of Rule 205. However, we anticipate the need for such approvals to be rare.

submittal explains that the Maricopa Association of Governments (MAG) [42] will address this by adding 1,000 tpy of NO_X and 500 tpy of VOC emissions into the emissions inventory for its new ozone ''Moderate'' area plan for the 2015 ozone NAAQS.[43] This line item represents the maximum number of MERCs and/or nonroad engine emission reduction credits (NERCs) that will be creditable through Rule 205 and MCAQD Rule 204, ''Emission Offsets Generated by Voluntary Nonroad Engine Emission Reductions,'' revised on November 5, 2025 (''Rule 204'').[44] Effectively, this ensures MERCs and NERCs generated through Rules 205 and 204, respectively, will be excluded from SIP modeling and cannot be accounted for in the State's attainment demonstration for the 2015 ozone NAAQS. Regarding transportation conformity, the MCAQD Rule 205 submittal explains that before the start of modeling for a transportation plan or transportation improvement program conformity, the MCAQD will notify MAG of each individual MERC project so that the reductions from each project are not included in the corresponding transportation conformity analysis, consistent with the interagency consultation process required by 40 CFR 93.112.[45]

These actions by the MCAQD and MAG related to attainment plans and transportation conformity ensure that Rule 205 will only allow surplus emissions reductions to be creditable for NNSR offset purposes and that Arizona will not ''double-count'' emissions reductions when developing SIP attainment demonstrations.

Comment 5.a: The commenter asserted that Rule 205 is deficient because it does not specify whether ongoing monitoring, recordkeeping, and reporting requirements applicable to MERC generators must be preserved when the generator's business changes hands, restructures, expands, or shuts down. The commenter asserted that this omission is a legal defect.

Response 5.a: We disagree that Rule 205 is deficient because it does not specifically state what happens to ongoing requirements in Rule 205 when the MERC generator's business changes hands, restructures, expands, or shuts down. Under Rule 205, MERC generators will be issued permits that contain the applicable monitoring, recordkeeping, and reporting requirements.[46] If the owner/operator named on the permit were to change as a result of a business changing hands, restructuring, expanding, or shutting down, the MCAQD's SIP-approved New Source Review (NSR) program provides a process for ensuring that permit requirements remain in effect, and this process would apply to MERC generators.[47] MCAQD Rule 200, ''Permit Requirements,'' revised on December 11, 2019 (''Rule 200''), describes the requirements for transferring a permit, including, but not limited to, a signed statement and acceptance of responsibility for the permit by the new permit holder.[48] To the extent the commenter is concerned about the integrity of MERCs as a result of a business changing hands, restructuring, expanding, or shutting down, Rule 205 contains provisions for ensuring the ongoing integrity of MERCs and includes requirements to address potential shortfalls in emissions reductions.[49]

Comment 5.b: The commenter stated that the requirement for MERC generators in Rule 205 to track, for 20 years, that a new or retrofitted vehicle is only replaced with a vehicle that is certified to the same or lower emission standards is a ''de facto constraint on future fleet decisions.'' As an example, the commenter stated that a company that switches to electric vehicles but leases vehicles on a three-year cycle could be prohibited from reverting to internal combustion engines at the end of the lease term, which the commenter asserted would effectively function as a long-term electric vehicle mandate. The commenter concluded that the rule therefore ''raises significant preemption concerns absent a [CAA] [s]ection 209 waiver.''

Response 5.b: We disagree that Rule 205 functions as a long-term electric vehicle mandate that raises preemption concerns under CAA section 209. CAA section 209(a) prohibits States from setting or enforcing new motor vehicle emissions standards unless a waiver is granted by the EPA under CAA section 209(b).[50] Here, there is no State action to set or enforce a new motor vehicle emissions standard. Rule 205 is merely an administrative rule to facilitate the creation and trading of MERCs for use as offsets by stationary sources. Participation in the MERC generating program is voluntary. If a fleet owner or operator voluntarily *chooses* to generate MERCs by replacing a vehicle with an electric vehicle, then Rule 205 requires the MERC generator to maintain the same level of emissions reductions for 20 years to meet the offset integrity criteria. As stated previously, Rule 205 is fuel neutral and does not restrict the type of vehicle replacement that qualifies for generating MERCs. If a MERC generator finds that replacing a vehicle with an electric vehicle would be too restrictive on future vehicle fleet decisions, then the MERC generator can choose a replacement vehicle type with emission rates the MERC generator can more confidently maintain.

IV. EPA Action

No comments were submitted that changed our assessment of the approvability of the MCAQD Rule 205 submittal as described in our proposed action. Therefore, as authorized in CAA section 110(k)(3), the EPA is approving the MCAQD Rule 205 submittal by adding MCAQD Rule 205 into the federally enforceable portion of the Arizona SIP and adding the MCAQD's EIP support document into the non-regulatory portion of the Arizona SIP.

V. Incorporation by Reference

In this document, 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 MCAQD

[42] MAG is a nonprofit Arizona corporation composed of elected officials from over 20 cities and towns, Maricopa County, Gila River Indian Community, and the Arizona Department of Transportation. MAG is the lead planning organization for Maricopa County that is responsible for conducting air quality modeling and preparing and demonstrating that the transportation plans and transportation conformity are consistent with air quality plans.

[43] MCAQD Rule 205 submittal, page 37.

[44] NERCs are ERCs generated from captive fleet nonroad engines, as defined in Rule 204. On November 14, 2025, Rule 204 was submitted to the EPA by the ADEQ for inclusion into the Maricopa County portion of the Arizona SIP. On October 8, 2026, the EPA proposed approval of Rule 204 into the Maricopa County portion of the Arizona SIP. *See* 91 FR 64321 (Oct. 8, 2026).

[45] MCAQD Rule 205 submittal, page 37. For a fuller discussion on how Rule 205 meets the surplus criterion, please see pages 9 through 14 of the TSD for this action.

[46] Rule 205, sections 301.2b and 301.3b.

[47] The NSR program refers to the requirements for SIPs to contain permitting programs for the preconstruction review of new and modified stationary sources under the CAA. The program consists of three main components: the minor NSR program at 40 CFR 51.160 through 51.164, the NNSR program at 40 CFR 51.165, and the Prevention of Significant Deterioration program at 40 CFR 51.166. The MCAQD has SIP-approved rules for all three components.

[48] Rule 200, section 404, as approved into the SIP. *See* 87 FR 8418 (Feb. 15, 2022).

[49] Rule 205, section 401.

[50] CAA section 209(a) states: ''No State or any political subdivision thereof shall adopt or attempt to enforce any standard relating to the control of emissions from new motor vehicles or new motor vehicle engines subject to this part. No State shall require certification, inspection, or any other approval relating to the control of emissions from any new motor vehicle or new motor vehicle engine as condition precedent to the initial retail sale, titling (if any), or registration of such motor vehicle, motor vehicle engine, or equipment.''

Rule 205, ''Emission Offsets Generated by Voluntary Mobile Source Emission Reductions,'' revised on May 21, 2025, which establishes a federally enforceable program allowing fleet vehicle owners/operators to generate ERCs through voluntary on-road mobile source emissions reductions under the CAA. Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under CAA sections 110 and 113 as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[51] The EPA has made, and will continue to make, these documents available through *https://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).

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, the 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 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);
- Is not an Executive Order 14192 (90 FR 9065, February 6, 2025) regulatory action because this action is not significant 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 subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- 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.

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).

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 January 4, 2027. 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* CAA section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: November 2, 2026.

Michael Martucci,

Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 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 D—Arizona

■ 2. Amend § 52.120 by:

■ a. In paragraph (c), amending Table 4, under the subheading ''Regulations II—Permits and Fees'', adding an entry for ''Rule 205'' after the entry for ''Rule 200''; and

■ b. In paragraph (e), amending Table 1, under the subheading ''Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas'' adding an entry for ''Revision to Arizona's State Implementation Plan (SIP) Addition of Rule 205 to the Maricopa County Air Pollution Control Regulations (MCAPCR), Appendix 18–Economic Incentive Program Support Document'' after the entry for ''Revision of Rule 322 of the Maricopa County Air Pollution Control Regulations, Appendix 12: RACT Analyses Submitted to the Maricopa County Air Quality Department from the Arizona Public Service and the Salt River Project, only''.

The additions read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

[51] 62 FR 27968 (May 22, 1997).

TABLE 4 TO PARAGRAPH (c)—EPA-APPROVED MARICOPA COUNTY AIR POLLUTION CONTROL REGULATIONS

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
* *	*	*	* *	*
Regulation II—Permits and Fees				
* *	*	*	* *	*
Rule 205	Emission Offsets Generated by Voluntary Mobile Source Emission Reductions.	May 21, 2025	November 5, 2026, 91 FR [INSERT FEDERAL REGISTER PAGE WHERE THE DOCUMENT BEGINS].	Submitted on May 30, 2025.
* *	*	*	* *	*

* * * * * (e) * * *

TABLE 1—EPA-APPROVED NON-REGULATORY AND QUASI-REGULATORY MEASURES

[Excluding certain resolutions and statutes, which are listed in tables 2 and 3, respectively][1]

Name of SIP provision	Applicable geographic or nonattainment area or title/subject	State submittal date	EPA approval date	Explanation
The State of Arizona Air Pollution Control Implementation Plan				
* *	*	*	* *	*
Part D Elements and Plans for the Metropolitan Phoenix and Tuscon Areas				
* *	*	*	* *	*
Revision to Arizona's State Implementation Plan (SIP) Addition of Rule 205 to the Maricopa County Air Pollution Control Regulations (MCAPCR), Appendix 18—Economic Incentive Program Support Document.	Maricopa County	May 30, 2025	November 5, 2026, 91 FR [INSERT FEDERAL REGISTER PAGE WHERE THE DOCUMENT BEGINS].	Adopted by the Maricopa County Air Quality Department on May 21, 2025.
* *	*	*	* *	*

[1] Table 1 is divided into three parts: Clean Air Act Section 110(a)(2) State Implementation Plan Elements (excluding Part D Elements and Plans), Part D Elements and Plans (other than for the Metropolitan Phoenix or Tucson Areas), and Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas.

* * * * *

[FR Doc. 2026–22647 Filed 11–4–26; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R03–OAR–2023–0230; FRL–9329–03–R3]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; West Virginia; Control of Emissions From Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a Clean Air Act (CAA) section 111(d) plan revision submitted by the West Virginia Department of Environmental Protection (WVDEP). This revision updates the plan to include changes made to Emissions Guidelines and Compliance Times for municipal solid waste (MSW) landfills. This action is being taken under the Clean Air Act (CAA).

DATES: This final rule is effective on December 7, 2026. The incorporation by reference of certain material listed in the rule is approved by the Director of the Federal Register as of December 7, 2026. The incorporation by reference of certain other material listed in the rule was approved by the Director of the Federal Register as of December 23, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2023–0230. All documents in the docket are listed on the *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 *www.regulations.gov,* or please contact the person identified