

EPA-APPROVED GEORGIA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
391–3–1–.03(11).	Permit by Rule	7/23/2018	11/22/2019, [Insert citation of publication].	Except sections (a)–(b)(5) and (b)(7)–(b)(10), approved on 2/9/2010 with a State-effective date of 7/20/2005; section (b)(6), approved on 3/13/2000 with a State-effective date of 12/25/1997; and the phrase “or enforceable as a practical matter” in section .03(11)(b)11.(i), which is not in the SIP.

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 [FR Doc. 2019–25286 Filed 11–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R03–OAR–2019–0187; FRL–9999–80–Region 3]

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 submitted by the West Virginia Department of Environmental Protection (WVDEP). This plan was submitted to fulfill the requirements of the CAA and in response to EPA’s promulgation of Emissions Guidelines and Compliance Times for municipal solid waste (MSW) landfills. The West Virginia plan establishes emission limits for existing MSW landfills, and provides for the implementation and enforcement of those limits.

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

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–EPA–R03–OAR–2019–0187. 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.

FOR FURTHER INFORMATION CONTACT: Mike Gordon, Permits Branch (3AD10), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2039. Mr. Gordon can also be reached via electronic mail at gordon.mike@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 1, 2019 (84 FR 31278), EPA published a notice of proposed rulemaking (NPRM) for the State of West Virginia. In the NPRM, EPA proposed approval of a Clean Air Act (CAA) section 111(d) plan submitted by the WVDEP. The formal State Plan was submitted by West Virginia on September 13, 2018.

II. Summary of State Plan and EPA Analysis

EPA has reviewed the West Virginia section 111(d) plan submittal in the context of the requirements of 40 CFR part 60, subparts B and Cf, and part 62, subpart A. In this action, EPA is determining that the submitted section 111(d) plan meets the above-cited requirements. Included within the section 111(d) plan are regulations under the West Virginia Code, specifically, West Virginia legislative rule 45 C.S.R. 23, entitled “Control of Air Pollution from Municipal Solid Waste Landfills.” A detailed explanation of the rationale behind this proposed approval is available in the Technical Support Document (TSD).

Other specific requirements of West Virginia’s State Plan for MSW landfills and the rationale for EPA’s proposed

action are explained in the NPRM and will not be restated here. No public comments were received on the NPRM.

III. Final Action

EPA is approving the West Virginia section 111(d) plan for MSW landfills submitted pursuant to 40 CFR part 60, subpart Cf. Therefore, EPA is amending 40 CFR part 62, subpart XX to reflect this action. The scope of the approval of the section 111(d) plan is limited to the provisions of 40 CFR parts 60 and 62 for existing MSW landfills, as referenced in the emission guidelines, subpart Cf. The EPA Administrator continues to retain authority for approval of alternative methods to determine the nonmethane organic compound concentration or a site-specific methane generation rate constant (k), as stipulated in 40 CFR 60.30f(c), as well as section 4.8.b, “Implementation of Emission Guidelines for Existing MSW Landfills,” of West Virginia’s 111(d) plan submittal.

IV. Incorporation by Reference

In accordance with the requirements of 1 CFR 51.5, EPA is finalizing regulatory text that includes the incorporation by reference of West Virginia Code, specifically, West Virginia legislative rule 45 C.S.R. 23, effective June 1, 2018, entitled “Control of Air Pollution from Municipal Solid Waste Landfills,” which is part of the CAA section 111(d) plan applicable to existing MSW landfills in West Virginia as discussed in section II of this preamble. The regulatory provisions of 45 C.S.R. 23 establish emission standards and compliance times for the control of methane and other organic compounds from certain existing MSW landfills located in West Virginia that commenced construction, modification, or reconstruction on or before July 17, 2014. These provisions set forth requirements meeting criteria promulgated by EPA at 40 CFR part 60, subpart Cf. EPA has made, and will continue to make, 45 C.S.R. 23, as well as the entire West Virginia plan, generally available through

www.regulations.gov, Docket No. EPA-R03-OAR-2019-0187, 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). This incorporation by reference has been approved by the Office of the Federal Register and the Plans are federally enforceable under the CAA as of the effective date of this final rulemaking.

V. Statutory and Executive Order Reviews

A. General Requirements

Under the Clean Air Act, the Administrator is required to approve section 111(d) state plan submissions that comply with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7411(d); 40 CFR part 60, subparts B and Cf; and 40 CFR part 62, subpart A. Thus, in reviewing CAA section 111(d) state plan submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Act and implementing regulations. 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 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 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 CAA; and

- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the State Plan 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.

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 21, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving West Virginia's State Plan for existing MSW landfills may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection, Air pollution control, Landfills,

Incorporation by reference, Intergovernmental relations, Methane, Ozone, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: August 27, 2019.

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Regional Administrator, Region III.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 62 as follows:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

Subpart XX—West Virginia

■ 2. Section 62.12125 is revised to read as follows:

§ 62.12125 Identification of plan.

(a) West Virginia 111(d) plan for municipal solid waste landfills, including delegation of Federal plan compliance schedule and reporting requirements, as submitted to the Environmental Protection Agency on May 29, 1998, and as amended on May 15, 2000, and December 20, 2000, to implement 40 CFR part 60, subpart Cc.

(b)(1) Control of landfill gas emissions from existing municipal solid waste landfills, submitted by the West Virginia Department of Environmental Protection on September 13, 2018, to implement 40 CFR part 60, subpart Cf. The Plan includes regulatory provisions cited in paragraph (c) of this section, which the EPA incorporates by reference.

(2) After December 23, 2019, the substantive requirements of the municipal solid waste landfills state plan are contained in paragraph (b) of this section and owners and operators of municipal solid waste landfills in West Virginia must comply with the requirements in paragraph (b) of this section.

(c) *Incorporation by reference.* (1) The material incorporated by reference in this section was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the material is available electronically through www.regulations.gov, Docket No. EPA-R03-OAR-2019-0187, or at the EPA Region III office, 1650 Arch Street, Philadelphia, PA 19103, 215-814-5000. Copies may be inspected at the National Archives and Records Administration (NARA). For information on the

availability of this material at NARA, email fedreg.legal@nara.gov or go to: www.archives.gov/federal-register/cfr/ibr-locations.html.

(2) State of West Virginia, Secretary of State, Code of State Regulations.

(i) 45 CSR 23: West Virginia legislative rule; Title 45, Department of Environmental Protection, Air Quality; Series 23, Control of Air Pollution from Municipal Solid Waste Landfills, effective June 1, 2018.

(ii) [Reserved]

■ 3. Section 62.12126 is revised to read as follows:

§ 62.12126 Identification of sources.

(a) The plan in § 62.12125(a) applies to all existing West Virginia municipal solid waste landfills for which construction, reconstruction, or modification was commenced before May 30, 1991 and that accepted waste at any time since November 8, 1987, or that have additional capacity available for future waste deposition, as described in 40 CFR part 60, subpart Cc.

(b) The plan in § 62.12125(b) applies to all existing municipal solid waste landfills under the jurisdiction of the West Virginia Department of Environmental Protection for which construction, reconstruction, or modification was commenced on or before July 17, 2014.

■ 4. Section 62.12127 is revised to read as follows:

§ 62.12127 Effective date.

(a) The effective date of the plan submitted on May 29, 1998, and as amended on May 15, 2000 by the West Virginia Department of Environmental Protection for municipal solid waste landfills is July 23, 2001.

(b) The effective date of the plan submitted on September 13, 2018 by the West Virginia Department of Environmental Protection for municipal solid waste landfills is December 23, 2019.

[FR Doc. 2019-25168 Filed 11-21-19; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

HHS Policy for the Protection of Human Research Subjects

AGENCY: Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS)

ACTION: Determination of Exception: required use of single institutional review board for cooperative research.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS), excepts two categories of research from the required use of a single institutional review board (IRB) to review cooperative research under the HHS regulations for the protection of human subjects. This determination is specific to research conducted or supported by HHS.

DATES: This exception is applicable as of November 22, 2019.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Director, Division of Policy and Assurances, Office for Human Research Protections (OHRP), Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone: 240-453-6900 or 1-866-447-4777; facsimile: 240-453-8409; email: Irene.stith-coleman@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Regulatory History

In a final rule published on January 19, 2017, HHS and other Federal departments and agencies revised the Federal Policy for the Protection of Human Subjects (the “Common Rule”), codified with respect to HHS at subpart A of 45 CFR part 46. The Common Rule is followed by 19 other Federal departments and agencies, either as Common Rule signatories, or as required by Executive Order or statute. The revised Common Rule, including amendments made by a January 22, 2018 interim final rule (83 FR 2885) and June 19, 2018 final rule (83 FR 28497) (also referred to as the “2018 Requirements”), became effective on July 19, 2018.

The revised Common Rule requires that U.S. institutions engaged in cooperative research must rely on a single institutional review board (IRB) to review and approve the portion of the research conducted at domestic sites. See 45 CFR 46.114(b). The compliance date for the single IRB requirement is January 20, 2020.

The revised Common Rule applies to all research initially approved by an IRB on or after January 21, 2019. See 45 CFR 46.101(l)(5). As of January 20, 2020, the compliance date for the single IRB requirement, all cooperative research subject to the revised Common Rule will be required to use a single IRB, whether

the research was initially approved by a single IRB or multiple IRBs.

Regulatory Allowance of Exceptions to Single IRB Review Requirement

The revised Common Rule provides that the agency conducting or supporting cooperative research may except the research from the single IRB mandate. To do so, the agency must both determine and document that using a single IRB is not appropriate in the particular context. See 45 CFR 46.114(b)(2).

Research Contexts Qualifying for Exception

With respect to HHS-conducted or supported research, OHRP has determined that the following research is excepted from the single IRB mandate: (1) Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB approved the research before January 20, 2020, or (2) cooperative research conducted or supported by NIH if either (a) the NIH single IRB policy¹ does not apply, and the research was initially approved by an IRB before January 20, 2020, or (b) NIH excepted the research from its single IRB policy before January 20, 2020.

Cooperative Research Approved Before January 20, 2020

In May 2019, the Association of American Medical Colleges (AAMC), the Council on Governmental Relations (COGR), the Association of American Universities (AAU), and the Association of Public Land-Grant Universities (APLGU) wrote to the director of OHRP expressing concern regarding the application of the single IRB requirement to cooperative research subject to the revised Common Rule when the research was approved before January 20, 2020 (available at <https://www.aamc.org/download/497410/data/finaljointassociationlettertoohrponingleirb.pdf>). The organizations asserted that much of the research community did not fully understand the way this requirement would operate, and informed OHRP that shifting a multisite study in midstream to a single IRB review system would be difficult and expensive. On this basis, the organizations requested that OHRP issue an exception to the single IRB requirement for cooperative research conducted under the revised Common

¹ See “Guidance on Exceptions to the NIH Single IRB Policy” released October 11, 2017. Available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-003.html>.