

included in this classification, see § 882.5950 of this chapter.

(b) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices." For availability of this guidance document, see § 870.1(e).

## PART 882—NEUROLOGICAL DEVICES

■ 3. The authority citation for 21 CFR part 882 continues to read as follows:

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

■ 4. Section 882.5950 is revised to read as follows:

### § 882.5950 Neurovascular embolization device.

(a) *Identification.* A neurovascular embolization device is an intravascular implant intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in other vascular applications are also not included in this classification, see § 870.3300.

(b) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices." For availability of this guidance document, see § 882.1(e).

Dated: December 15, 2004.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 04-28437 Filed 12-28-04; 8:45 am]

BILLING CODE 4160-01-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[R03-OAR-2004-VA-0005; FRL-7853-7]

### Approval and Promulgation of Air Quality Implementation Plans; Virginia; Approval of the Control of VOC Emissions From Municipal Solid Waste Landfills in Northern Virginia

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

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve a revision to the

Commonwealth of Virginia (the Commonwealth) State Implementation Plan (SIP). The revision establishes regulations for the control of volatile organic compound (VOC) emissions from municipal solid waste landfills (MSWLs) located in the Northern Virginia Portion of the Metropolitan Washington, D.C. Ozone Nonattainment Area. (Northern Virginia). EPA is approving this revision to the SIP in accordance with the requirements of the Clean Air Act (CAA or the Act).

**DATES:** This rule is effective on February 28, 2005, without further notice, unless EPA receives adverse written comment by January 28, 2005. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Regional Material in Edoctet (RME) ID Number R03-OAR-2004-VA-0005 by one of the following methods:

A. Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. Agency Web site: <http://www.docket.epa.gov/rmepub/> RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

C. E-mail: [Morris.Makeba@epa.gov](mailto:Morris.Makeba@epa.gov).

D. Mail: R03-OAR-2003-VA-0005, Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

E. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to RME ID No. R03-OAR-2004-VA-0005. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.docket.epa.gov/rmepub/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, [regulations.gov](http://www.regulations.gov) or e-mail. The EPA RME and the Federal [regulations.gov](http://www.regulations.gov) Web sites are an "anonymous access"

system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

**Docket:** All documents in the electronic docket are listed in the RME index at <http://www.docket.epa.gov/rmepub/>. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

**FOR FURTHER INFORMATION CONTACT:** Janice Lewis, (215) 814-2185, or by e-mail at [lewis.janice@epa.gov](mailto:lewis.janice@epa.gov).

## SUPPLEMENTARY INFORMATION:

### I. Background

On February 12, 2004, the Commonwealth submitted a revision to its State Implementation Plan (SIP). The SIP revision consists of regulations to control VOC emissions from Municipal Solid Waste Landfills (MSWLs) in the Northern Virginia portion of the Metropolitan Washington, D.C. Ozone Nonattainment Area. The regulation establishes emission standards for MSWLs, as well as operational, monitoring and reporting requirements. This revision applies to the Northern Virginia portion of the Metropolitan Washington, D.C. Ozone Nonattainment Area, and is not intended to apply to

any other portion of the Commonwealth.

## II. Summary of SIP Revision

The Commonwealth's February 12, 2004 submittal includes regulations that apply to MSWLs which commenced construction, reconstruction, or modification before May 30, 1991 in the Northern Virginia VOC Control Area (Arlington County, Alexandria City, Fairfax County, Fairfax City, Falls Church City, Loudon County, Manassas City, Manassas Park City, Prince William County, and Stafford County) as designated in 9 VAC 5–20–206. The landfill design capacity applicability criteria is 1.0 million megagrams (Mg) or more and 1.0 million cubic meters. The emission rate applicability criteria is emissions of nonmethane organic compound (NMOCs) greater than or equal to 23 Mg per year. The primary components of MSWL emissions are methane and NMOCs. VOCs are a component of NMOCs.

Landfills that have a design capacity greater than or equal to 1.0 million Mg and 1.0 million cubic meters are required to test and report their emission rate annually. If the NMOC emission rate exceeds 23 Mg per year, the MSWL is required to submit plans for and to install a collection system and control system for the subject emissions. The regulation establishes specifications for the collection and control systems and provide test methods and calculation procedures for estimating NMOC emission rates. In addition, the regulation provides compliance schedules and reporting requirements, and incorporates control and equipment maintenance and malfunction provisions.

## III. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995 Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) "privilege" for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the

violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) that are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information "required by law," including documents and information "required by Federal law to maintain program delegation, authorization or approval," since Virginia must "enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. . . ." The opinion concludes that "[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval."

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that "[t]o the extent consistent with requirements imposed by Federal law," any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since "no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity."

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because

EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the Clean Air Act, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by this, or any, state audit privilege or immunity law.

## IV. Final Action

EPA is approving the revision to the Commonwealth's SIP which establish regulations for the control of emission of volatile organic compound (VOC) emissions from municipal solid waste landfills (MSWLs) located in Northern Virginia portion of the Metropolitan Washington, D.C. Ozone Nonattainment Area (Northern Virginia). This revision applies only to the Northern Virginia Ozone Nonattainment Area, and is not intended to apply to any other part of the Commonwealth.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. However, in the "Proposed Rules" section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on February 28, 2005 without further notice unless EPA receives adverse comment by January 28, 2005. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

## V. Statutory and Executive Order Reviews

### A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the

Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it 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). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045

“Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA’s role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

*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 rule 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**. This rule 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 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 February 28, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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 the Commonwealth of Virginia’s regulation to require municipal solid waste landfills in Northern Virginia to control emissions of volatile organic compounds may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

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

Environmental protection, Air pollution control, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 14, 2004.

**Donald S. Welsh,**  
*Regional Administrator, Region III.*

■ 40 CFR part 52 is amended as follows:

**PART 52—[AMENDED]**

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

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

**Subpart VV—Virginia**

■ 2. Section 52.2420, the table in paragraph (c) is amended by adding entries under chapter 40, part II to read as follows:

**§ 52.2420 Identification of plan.**

\* \* \* \* \*

(c) *EPA approved regulations and statutes.*

EPA—APPROVED REGULATIONS AND STATUTES IN THE VIRGINIA SIP

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation (former SIP section)
*	*	*	*	*
Chapter 40 Existing Stationary Sources				

## EPA—APPROVED REGULATIONS AND STATUTES IN THE VIRGINIA SIP—Continued

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation (former SIP section)
*	*	*	*	*
<b>Part II Emission Standards</b>				
*	*	*	*	*
<b>Article 43 Municipal Solid Waste Landfills (Rule 4-43)</b>				
5-40-5800	Applicability and Designation of Affected Facility.	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5810	Definitions .....	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5820	Standards for Air Emissions .....	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5822	Operational standards for collection and control systems.	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5824	Specifications for active collection systems ..	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5850	Compliance .....	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5855	Compliance schedule .....	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5860	Test methods and procedures .....	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5870	Monitoring .....	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5880	Reporting .....	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5890	Recordkeeping .....	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5900	Registration .....	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5910	Facility and control equipment maintenance or malfunction.	1/29/04	12/29/04	[Insert page number where the document begins].
5-40-5920	Permits .....	1/29/04	12/29/04	[Insert page number where the document begins].

[FR Doc. 04-28351 Filed 12-28-04; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 52**

[R03-OAR-2004-DC-0004; FRL-7853-5]

**Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; VOC Emission Standards for Portable Fuel Containers and Spouts****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve revisions to the District of Columbia State Implementation Plan (SIP). Specifically, EPA is approving new emission standards for portable fuel containers and spouts sold, supplied, offered for sale, or manufactured for sale in the District of Columbia (the District). EPA

is approving the new portable fuel container and spouts standards to reduce emissions of volatile organic compounds (VOC) in accordance with the requirements of the Clean Air Act (CAA or the Act).

**DATES:** This rule is effective on February 28, 2005 without further notice, unless EPA receives adverse written comment by January 28, 2005. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Regional Material in EDocket (RME) ID Number R03-OAR-2004-DC-0004 by one of the following methods:

A. Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. Agency Web site: <http://www.docket.epa.gov/rmepub/> RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow

the on-line instructions for submitting comments.

C. E-mail: [morris.makeba@epa.gov](mailto:morris.makeba@epa.gov).

D. Mail: R03-OAR-2004-DC-0004, Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

E. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to RME ID No. R03-OAR-2004-DC-0004. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.docket.epa.gov/rmepub/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit