

adversely affect the safety, effectiveness, or availability of the specified lots, batches, or other units of the in vitro diagnostic product for human use that are or will be held in the Strategic National Stockpile;

(iv) Describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product, given the anticipated circumstances of use of the product;

(v) Provide a draft of the proposed labeling of the specified lots, batches, or other units of the in vitro diagnostic products for human use subject to the exception or alternative; and

(vi) Provide any other information requested by the Center Director in support of the request.

(c) The Center Director must respond in writing to all requests under this section. The Center Director may impose appropriate conditions or safeguards when granting such an exception or alternative under this section.

(d) A grant of an exception or alternative under this section will include any safeguards or conditions deemed appropriate by the Center Director to ensure that the labeling of the product subject to the exception or alternative includes the information necessary for the safe and effective use of the product, given the anticipated circumstances of use.

(e) If the Center Director grants a request for an exception or alternative to the labeling requirements under this section:

(1) The Center Director may determine that the submission and grant of a written request under this section satisfies the provisions relating to premarket notification submissions under § 807.81(a)(3) of this chapter.

(2)(i) For a Premarket Approval Application (PMA)-approved in vitro diagnostic product for human use, the submission and grant of a written request under this section satisfies the provisions relating to submission of PMA supplements under § 814.39 of this chapter; however,

(ii) The grant of the request must be identified in a periodic report under § 814.84 of this chapter.

(f) The Center Director may grant an exception or alternative under this section to the following provisions of this part, to the extent that the requirements in these provisions are not explicitly required by statute:

(1) § 809.10(a)(1) through (a)(6) and (a)(9);

(2) § 809.10(b);

(3) § 809.10(c)(2);

(4) § 809.10(d)(1)(i) through (d)(1)(v), (d)(1)(viii), and (d)(2); and

(5) § 809.10(e)(1)(i) through (e)(1)(vi) and (e)(1)(ix) through (e)(1)(xi).

#### **PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS**

■ 17. The authority citation for 21 CFR part 812 continues to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 18. Section 812.5 is amended by adding paragraph (d) to read as follows:

##### **§ 812.5 Labeling of investigational devices.**

\* \* \* \* \*

(d) The appropriate FDA Center Director, according to the procedures set forth in § 801.128 or § 809.11 of this chapter, may grant an exception or alternative to the provisions in paragraphs (a) and (c) of this section, to the extent that these provisions are not explicitly required by statute, for specified lots, batches, or other units of a device that are or will be included in the Strategic National Stockpile.

#### **PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES**

■ 19. The authority citation for 21 CFR part 814 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 20. Section 814.39 is amended by adding paragraph (g) to read as follows:

##### **§ 814.39 PMA Supplements.**

\* \* \* \* \*

(g) The submission and grant of a written request for an exception or alternative under § 801.128 or § 809.11 of this chapter satisfies the requirement in paragraph (a) of this section.

■ 21. Section 814.84 is amended by adding paragraph (b)(3) to read as follows:

##### **§ 814.84 Reports.**

\* \* \* \* \*

(b) \* \* \*

(3) Identify changes made pursuant to an exception or alternative granted under § 801.128 or § 809.11 of this chapter.

Dated: December 20, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–25165 Filed 12–27–07; 8:45 am]

**BILLING CODE 4160–01–S**

#### **ENVIRONMENTAL PROTECTION AGENCY**

##### **40 CFR Part 52**

[EPA–R03–OAR–2007–0381; FRL–8510–3]

#### **Approval and Promulgation of Air Quality Implementation Plans; Virginia; Clean Air Interstate Rule Budget Trading Programs**

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

**ACTION:** Final rule.

**SUMMARY:** EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia. This revision establishes budget trading programs for nitrogen oxides (NO<sub>x</sub>) annual, NO<sub>x</sub> ozone season, and sulfur dioxides (SO<sub>2</sub>) annual emissions to address the requirements of EPA's Clean Air Interstate Rule (CAIR). Virginia will meet its CAIR requirements by participating in the EPA-administered regional cap-and-trade program for NO<sub>x</sub> annual, NO<sub>x</sub> ozone season, and SO<sub>2</sub> annual emissions. EPA is determining that the SIP revision fully implements the CAIR requirements for Virginia. Therefore, as a consequence of the SIP approval, EPA will also withdraw the CAIR Federal Implementation Plan (FIP) that addresses NO<sub>x</sub> annual, NO<sub>x</sub> ozone season, and SO<sub>2</sub> annual emissions in Virginia.

**EFFECTIVE DATE:** The final rule is effective on December 28, 2007.

**ADDRESSES:** EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2007–0381. All documents in the electronic docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, i.e., 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 either electronically at [www.regulations.gov](http://www.regulations.gov) 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:** Marilyn Powers, (215) 814–2308 or by e-mail at [powers.marilyn@epa.gov](mailto:powers.marilyn@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

On March 30, 2007, and supplemented on April 30, 2007 and June 11, 2007, the Virginia Department of Environmental Quality (VADEQ) submitted a CAIR SIP revision to meet the requirements of CAIR, which was promulgated on May 12, 2005 (70 FR 25162), and subsequently revised on April 28, 2006, and December 13, 2006. The SIP revision is comprised of new regulations under 9 VAC 5 Chapter 140 of the Virginia Code as follows: Part II—NO<sub>x</sub> Annual Trading Program; Part III—NO<sub>x</sub> Ozone Season Trading Program; and Part IV—SO<sub>2</sub> Annual Trading Program. The regulations address all the requirements of the part 96 model rules set forth in the May 12, 2005 CAIR rulemaking.

On September 25, 2007 (72 FR 54385), EPA published a notice of proposed rulemaking (NPR) to approve Virginia's CAIR SIP revision. A detailed discussion of the CAIR requirements, Virginia's CAIR submittal, and EPA's rationale for approval of Virginia's CAIR SIP revision may be found in the NPR and will not be repeated here. On October 24, 2007, EPA received adverse comments from the State of Connecticut Department of Environmental Protection.

**II. Public Comments and EPA Responses**

*Comment:* On October 24, 2007, the Connecticut Department of Environmental Protection (CTDEP) submitted adverse comments on EPA's proposed approval of Virginia's CAIR SIP revision. CTDEP encourages EPA to approve state programs adopted to meet the emission reduction requirements of CAIR. However, it argues that before approving state CAIR plans, EPA should evaluate individually and in the aggregate each state's clean air programs. They argue such evaluation is necessary to ensure that each state's emissions do not significantly contribute to downwind nonattainment. CTDEP asserts its belief that the CAIR program does not ensure that the CAA section 110(a)(2)(D)(i) requirements to prohibit transported emissions that significantly contribute to nonattainment in Connecticut and other states will be met. CTDEP expresses concern that EPA is determining through this and other similar rulemakings that CAIR programs are sufficient to meet States' section 110(a)(2)(D)(i) obligations. CTDEP asserts, based on EPA and State modeling for CAIR, that the levels of transported pollution remaining after

CAIR implementation are large enough that, even with local controls, it may be difficult for Connecticut to attain the 8-hour ozone NAAQS by 2010. Finally, CTDEP questions EPA's determination that highly cost effective controls are adequate to address States' section 110(a)(2)(D)(i) obligations as compared to "reasonable cost" controls that could be achieved to effect more stringent NO<sub>x</sub> reductions.

*Response:* EPA does not agree that it is appropriate or necessary for EPA to conduct additional analysis before approving Virginia's CAIR SIP revision. In the CAIR rulemaking promulgated on May 12, 2005 (70 FR 25162), EPA established model rules for multi-State cap and trade programs for annual NO<sub>x</sub>, ozone season NO<sub>x</sub>, and annual SO<sub>2</sub> that States may choose to adopt to meet the required emissions reductions in a flexible and cost-effective manner. EPA requires States that wish to participate in the EPA-administered cap and trade program to use the model rule (with only limited flexibility to modify specific provisions) to ensure that all participating sources, regardless of which State in the CAIR region they are located, are subject to the same trading and allowance holding requirements. Virginia has chosen to participate in the cap and trade program administered by EPA and has chosen to adopt the model rules with modifications allowed by flexibilities in the model rule. EPA has evaluated Virginia's SIP revision and determined that Virginia is meeting its CAIR requirements. CTDEP does not challenge this determination. Thus, CTDEP's comments do not specifically pertain to any aspect of EPA's proposed action to approve the Virginia CAIR SIP revision. Rather, the comments appear to be directed broadly at EPA's decisions with regard to States' section 110(a)(2)(D)(i) obligations. These decisions were made by EPA in the context of the CAIR rulemaking, not in the proposed action to approve Virginia's CAIR SIP revision. Therefore, CTDEP's comments are not relevant to the proposed action. CTDEP had ample opportunity to submit comments both during the comment period for the proposed CAIR rulemaking of January 30, 2004 (70 FR 49708) and during the comment period for the proposed CAIR FIP of August 24, 2005 (70 FR 49708). EPA's proposal to approve Virginia's CAIR SIP did not reopen either the CAIR or CAIR FIP rulemakings. Consequently, CTDEP's comments are not relevant to this rulemaking, or timely with respect to the CAIR and CAIR FIP rulemakings. Thus, EPA does not believe it is necessary to conduct

additional analysis on whether Virginia or any other state satisfies the requirements of 110(a)(2)(D)(i) before approving Virginia's CAIR SIP submission.

**III. 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 CAA, 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 CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

#### IV. Final Action

EPA is approving Virginia's CAIR SIP revision submitted on March 30, 2007, and supplemented on April 30, 2007 and June 11, 2007. Under the SIP revision, Virginia will participate in the EPA-administered cap-and-trade programs for NO<sub>x</sub> annual, NO<sub>x</sub> ozone season, and SO<sub>2</sub> annual emissions. The SIP revision meets the applicable requirements in 40 CFR 51.123(o) and (aa), with regard to NO<sub>x</sub> annual and NO<sub>x</sub> ozone season emissions, and 40 CFR 51.124(o), with regard to SO<sub>2</sub> emissions. As a consequence of the SIP approval, the Administrator of EPA will issue, without providing an opportunity for a public hearing or an additional opportunity for written public comment, a final rule to withdraw the CAIR FIPs for SO<sub>2</sub>, NO<sub>x</sub> annual, and NO<sub>x</sub> ozone season emissions for Virginia.

#### V. Effective Date

EPA finds that there is good cause for this approval to become effective on the date of publication because a delayed effective date is unnecessary due to the nature of the approval, which allows the Commonwealth to make allocations under its CAIR rules. The expedited effective date for this action is authorized under both 5 U.S.C. 553(d)(1), which provides that rule actions may become effective less than 30 days after publication if the rule “grants or recognizes an exemption or relieves a restriction” and section 5 U.S.C. 553(d)(3), which allows an effective date less than 30 days after publication “as otherwise provided by the agency for good cause found and published with the rule.”

CAIR SIP approvals relieve states and CAIR sources within states from being subject to allowance allocation provisions in the CAIR FIPs that otherwise would apply to them, allowing States to make their own allowance allocations based on their SIP-approved State rule. The relief from these obligations is sufficient reason to allow an expedited effective date of this rule under 5 U.S.C. 553(d)(1).

#### VI. 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 requirement, 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 approves a state rule implementing a Federal standard. 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 26, 2008. 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 to approve Virginia’s CAIR SIP revision 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, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: December 13, 2007.

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

■ 40 CFR part 52 is amended as follows:

**PART 52—[AMENDED]**

■ 1. The authority citation for 40 CFR part 52 continues to read as follows:

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

**Subpart VV—Virginia**

■ 2. In § 52.2420, the table in paragraph (c) is amended by adding the entries for Chapter 140, Sections 1010 through 3880 to read as follows:

**§ 52.2420 Identification of plan.**

\* \* \* \* \*  
(c) \* \* \*

**EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES**

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
*	*	*	*	*
<b>Chapter 140 Regulation for Emissions Trading</b>				
*	*	*	*	*
<b>Part II NO<sub>x</sub> Annual Trading Program</b>				
<b>Article 1 CAIR-NO<sub>x</sub> Annual Trading Program General Provisions</b>				
5-140-1010 .....	Purpose .....	4/18/07	12/28/07 .....	[Insert page number where the document begins]
5-140-1020 .....	Definitions .....	4/18/07	12/28/07 [Insert page number where the document begins].	Except for definition of “Nonattainment condition”
5-140-1030 .....	Measurements, abbreviations, and acronyms.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1040 .....	Applicability .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1050 .....	Retired Unit Exemption .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1060 .....	Standard requirements .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1070 .....	Computation of time .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1080 .....	Appeal procedures .....	4/18/07	12/28/07 [Insert page number where the document begins].	
<b>Article 2 CAIR-designated Representative for CAIR NO<sub>x</sub> Sources</b>				
5-140-1100 .....	Authorization and responsibilities of CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1110 .....	Alternate CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1120 .....	Changing CAIR-designated representative and alternate CAIR-designated representative; changes in owners and operators.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1130 .....	Certificate of representation .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1140 .....	Objections concerning CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1150 .....	Delegation by CAIR-designated representative and alternate CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	

## EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES—Continued

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
<b>Article 3 Permits</b>				
5-140-1200 .....	General CAIR NO <sub>x</sub> Annual Trading Program permit requirements.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1210 .....	Submission of CAIR permit applications	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1220 .....	Information requirements for CAIR permit applications.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1230 .....	CAIR permit contents and term .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1240 .....	CAIR permit revisions .....	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 5 CAIR NO<sub>x</sub> Allowance Allocations</b>				
5-140-1400 .....	CAIR NO <sub>x</sub> Annual trading budgets .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1410 .....	Timing requirements for CAIR NO <sub>x</sub> allowance allocations.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1420 .....	CAIR NO <sub>x</sub> allowance allocations .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1430 .....	Compliance supplement pool .....	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 6 CAIR NO<sub>x</sub> Allowance Tracking System</b>				
5-140-1510 .....	Establishment of accounts .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1520 .....	Responsibilities of CAIR-authorized account representative.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1530 .....	Recordation of CAIR NO <sub>x</sub> allowance allocations.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1540 .....	Compliance with CAIR NO <sub>x</sub> emissions limitation.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1550 .....	Banking .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1560 .....	Account error .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1570 .....	Closing of general accounts .....	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 7 CAIR, NO<sub>x</sub> Allowance Transfers</b>				
5-140-1600 .....	Submission of CAIR NO <sub>x</sub> allowance transfers.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1610 .....	EPA recordation .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1620 .....	Notification .....	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 8 Monitoring and Reporting</b>				
5-140-1700 .....	General requirements .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1710 .....	Initial certification and recertification procedures.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1720 .....	Out of control periods .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1730 .....	Notifications .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1740 .....	Recordkeeping and reporting .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1750 .....	Petitions .....	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 9 CAIR NO<sub>x</sub> Opt-in Units</b>				
5-140-1800 .....	Applicability .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-1810 .....	General .....	4/18/07	12/28/07	[Insert page number where the document begins].

## EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES—Continued

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
5-140-1820 .....	CAIR-designated representative .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1830 .....	Applying for CAIR opt-in permit .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1840 .....	Opt-in process .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1850 .....	CAIR opt-in permit content .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1860 .....	Withdrawal from CAIR NO <sub>x</sub> Annual Trading Program.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1870 .....	Change in regulatory status .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-1880 .....	CAIR NO <sub>x</sub> allowance allocations to CAIR NO <sub>x</sub> opt-in units.	4/18/07	12/28/07 [Insert page number where the document begins].	

Part III NO<sub>x</sub> Ozone Season Trading ProgramArticle 1 CAIR NO<sub>x</sub> Ozone Season Trading Program General Provisions

5-140-2010 .....	Purpose .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2020 .....	Definitions .....	4/18/07	12/28/07 [Insert page number where the document begins].	Except for definition of "Nonattainment condition"
5-140-2030 .....	Measurements, abbreviations, and acronyms.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2040 .....	Applicability .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2050 .....	Retired unit exemption .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2060 .....	Standard requirements .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2070 .....	Computation of time .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2080 .....	Appeal procedures .....	4/18/07	12/28/07 [Insert page number where the document begins].	

Article 2 CAIR- Designated Representative for CAIR NO<sub>x</sub> Ozone Season Sources

5-140-2100 .....	Authorization and responsibilities of CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2110 .....	Alternate CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2120 .....	Changing CAIR-designated representative and alternate CAIR-designated representative; changes in owners and operators.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2130 .....	Certificate of representation .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2140 .....	Objections concerning CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2150 .....	Delegation by CAIR-designated representative and alternate CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	

## Article 3 Permits

5-140-2200 .....	General CAIR NO <sub>x</sub> Ozone Season Trading Program permit requirements.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2210 .....	Submission of CAIR permit applications	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2220 .....	Information requirements for CAIR permit applications.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2230 .....	CAIR permit contents and term .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2240 .....	CAIR permit revisions .....	4/18/07	12/28/07 [Insert page number where the document begins].	

## EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES—Continued

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
<b>Article 5 CAIR NO<sub>x</sub> Ozone Season Allowance Allocations</b>				
5-140-2400 .....	CAIR NO <sub>x</sub> Ozone Season trading budgets.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2405 .....	State trading budgets for nonelectric generating units.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2410 .....	Timing requirements for CAIR NO <sub>x</sub> Ozone Season allowance allocations.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2420 .....	CAIR NO <sub>x</sub> Ozone Season allowance allocations.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2430 .....	CAIR NO <sub>x</sub> Ozone Season allowance allocations for individual existing non-electric generating units.	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 6 CAIR NO<sub>x</sub> Ozone Season Allowance Tracking System</b>				
5-140-2510 .....	Establishment of accounts .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2520 .....	Responsibilities of CAIR-authorized account representative.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2530 .....	Recordation of CAIR NO <sub>x</sub> Ozone Season allowance allocations.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2540 .....	Compliance with CAIR NO <sub>x</sub> emissions limitation.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2550 .....	Banking .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2560 .....	Account error .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2570 .....	Closing of general accounts .....	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 7 CAIR NO<sub>x</sub> Ozone Season Allowance Transfers</b>				
5-140-2600 .....	Submission of CAIR NO <sub>x</sub> Ozone Season allowance transfers.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2610 .....	EPA recordation .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2620 .....	Notification .....	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 8 Monitoring and Reporting</b>				
5-140-2700 .....	General requirements .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2710 .....	Initial certification and recertification procedures.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2720 .....	Out of control periods .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2730 .....	Notifications .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2740 .....	Recordkeeping and reporting .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2750 .....	Petitions .....	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 9 CAIR NO<sub>x</sub> Ozone Season Opt-in Units</b>				
5-140-2800 .....	Applicability .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2810 .....	General .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2820 .....	CAIR-designated representative .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2830 .....	Applying for CAIR opt-in permit .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2840 .....	Opt-in process .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2850 .....	CAIR opt-in permit contents .....	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-2860 .....	Withdrawal from CAIR NO <sub>x</sub> Ozone Season Trading Program.	4/18/07	12/28/07	[Insert page number where the document begins].

## EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES—Continued

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
5-140-2870 .....	Change in regulatory status .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-2880 .....	CAIR NO <sub>x</sub> Ozone Season allowance allocations to CAIR NO <sub>x</sub> Ozone Season opt-in units.	4/18/07	12/28/07 [Insert page number where the document begins].	
<b>Part IV SO<sub>2</sub> Annual Trading Program</b>				
<b>Article 1 CAIR SO<sub>2</sub> Trading Program General Provisions</b>				
5-140-3010 .....	Purpose .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3020 .....	Definitions .....	4/18/07	12/28/07 [Insert page number where the document begins].	Except for definition of "Nonattainment condition"
5-140-3030 .....	Measurements, abbreviations, and acronyms.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3040 .....	Applicability .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3050 .....	Retired Unit Exemption .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3060 .....	Standard requirements .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3070 .....	Computation of time .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3080 .....	Appeal procedures .....	4/18/07	12/28/07 [Insert page number where the document begins].	
<b>Article 2 CAIR-designated Representative for CAIR SO<sub>2</sub> Sources</b>				
5-140-3100 .....	Authorization and responsibilities of CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3110 .....	Alternate CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3120 .....	Changing CAIR-designated representative and alternate CAIR-designated representative; changes in owners and operators.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3130 .....	Certificate of representation .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3140 .....	Objections concerning CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3150 .....	Delegation by CAIR-designated representative and alternate CAIR-designated representative.	4/18/07	12/28/07 [Insert page number where the document begins].	
<b>Article 3 Permits</b>				
5-140-3200 .....	General CAIR SO <sub>2</sub> Trading Program permit requirements.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3210 .....	Submission of CAIR permit applications	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3220 .....	Information requirements for CAIR permit applications.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3230 .....	CAIR permit contents and term .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3240 .....	CAIR permit revisions .....	4/18/07	12/28/07 [Insert page number where the document begins].	
<b>Article 5 CAIR SO<sub>2</sub> Allowance Allocations</b>				
5-140-3400 .....	State trading budgets .....	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3410 .....	Timing requirements for CAIR SO <sub>2</sub> allowance allocations.	4/18/07	12/28/07 [Insert page number where the document begins].	
5-140-3420 .....	CAIR SO <sub>2</sub> allowance allocations .....	4/18/07	12/28/07 [Insert page number where the document begins].	



EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES—Continued

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
<b>Article 6 CAIR SO<sub>2</sub> Allowance Tracking System</b>				
5-140-3510	Establishment of accounts	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3520	Responsibilities of CAIR-authorized account representative.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3530	Recordation of CAIR SO <sub>2</sub> allowances	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3540	Compliance with CAIR SO <sub>2</sub> emissions limitation.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3550	Banking	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3560	Account error	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3570	Closing of general accounts	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 7 CAIR SO<sub>2</sub> Allowance Transfers</b>				
5-140-3600	Submission of CAIR SO <sub>2</sub> allowance transfers.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3610	EPA recordation	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3620	Notification	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 8 Monitoring and Reporting</b>				
5-140-3700	General requirements	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3710	Initial certification and recertification procedures.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3720	Out of control periods	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3730	Notifications	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3740	Recordkeeping and reporting	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3750	Petitions	4/18/07	12/28/07	[Insert page number where the document begins].
<b>Article 9 CAIR SO<sub>2</sub> Opt-in Units</b>				
5-140-3800	Applicability	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3810	General	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3820	CAIR-designated representative	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3830	Applying for CAIR opt-in permit	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3840	Opt-in process	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3850	CAIR opt-in permit contents	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3860	Withdrawal from CAIR SO <sub>2</sub> Trading Program.	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3870	Change in regulatory status	4/18/07	12/28/07	[Insert page number where the document begins].
5-140-3880	CAIR SO <sub>2</sub> allowance allocations to CAIR SO <sub>2</sub> opt-in units.	4/18/07	12/28/07	[Insert page number where the document begins].
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[FR Doc. E7-24950 Filed 12-27-07; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 63**

[EPA-HQ-OAR-2005-0171; FRL-8512-1]

RIN 2060-AM14

**National Emission Standards for Hospital Ethylene Oxide Sterilizers**

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

**ACTION:** Final rule.

**SUMMARY:** EPA is issuing national emissions standards for new and existing hospital sterilizers that emit hazardous air pollutants and are area sources within the meaning of Clean Air Act section 112(a)(2). The final rule is based on EPA's determination as to what constitutes the generally available control technology or management practices for the hospital sterilizer area source category.

This action is being finalized as part of EPA's obligation to regulate area sources listed for regulation pursuant to Clean Air Act section 112(c)(3).

**DATES:** The final rule is effective on December 28, 2007.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2005-0171. All documents in the docket are listed in the Federal Docket Management System index at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., confidential business information 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 through [www.regulations.gov](http://www.regulations.gov) or in hard copy at the EPA Docket Center in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744. For the Air and Radiation Docket and Information Center, the telephone number is (202) 566-1742, the fax number is (202) 566-9744, the Web site is <http://www.epa.gov/oar/docket.html>, and the e-mail address is [a-and-r-Docket@epa.gov](mailto:a-and-r-Docket@epa.gov).

**FOR FURTHER INFORMATION CONTACT:** Mr. David Markwordt, Office of Air Planning and Standards, Sector Policies and Programs Division, Coatings and Chemicals Group (E143-01), Environmental Protection Agency, Research Triangle Park, NC 27711, telephone number: (919) 541-0837; fax number: (919) 541-0246; e-mail address: [markwordt.david@epa.gov](mailto:markwordt.david@epa.gov).

**SUPPLEMENTARY INFORMATION:** *Outline.* The information presented in this preamble is organized as follows:

- I. General Information
  - A. Does this action apply to me?
  - B. Where can I get a copy of this document?
  - C. Judicial Review
- II. Background Information for Final Area Source Standard
- III. Summary of the Final Rule and Significant Changes Since Proposal

- A. What is the affected source and the compliance date?
- B. What is required by the management practice?
- C. What are the testing and initial compliance requirements?
- D. What are the notification, recordkeeping, and reporting requirements?
- IV. Exemption of Certain Area Source Categories From Title V Permitting Requirements
- V. Summary of Comments and Responses
  - A. Proposed Alternative 1: Management Practice
  - B. Proposed Alternative 2: No Control
  - C. Add-on Controls
- VI. Summary of Environmental, Energy, Cost, and Economic Impacts
- VII. Statutory and Executive Order Reviews
  - A. Executive Order 12866: Regulatory Planning and Review
  - B. Paperwork Reduction Act
  - C. Regulatory Flexibility Act
  - D. Unfunded Mandates Reform Act
  - E. Executive Order 13132: Federalism
  - F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
  - G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
  - H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
  - I. National Technology Transfer and Advancement Act
  - J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
  - K. Congressional Review Act

**I. General Information**

*A. Does this action apply to me?*

The regulated categories and entities potentially affected by these final standards include:

Category	NAICS <sup>1</sup> code	Example of potentially regulated entities
General Medical and Surgical Hospitals .....	622110	Hospital sterilizers.
Specialty (Except Psychiatric and Substance Abuse) Hospitals .....	622310	Hospital sterilizers.

<sup>1</sup> North American Industrial Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. To determine whether your facility is regulated by this action, you should examine the applicability criteria in 40 CFR 63.10382 of subpart WWWW (National Emissions Standards for Hospital Ethylene Oxide Sterilizers). If you have any questions regarding the applicability of this action to a particular entity, consult either the air

permit authority for the entity or your EPA regional representative as listed in 40 CFR 63.13 of subpart A (General Provisions).

*B. Where can I get a copy of this document?*

In addition to being available in the docket, an electronic copy of this final action is also available on the Worldwide Web through the Technology Transfer Network (TTN). Following signature, a copy of this final

action will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at the following address: <http://www.epa.gov/ttn/oarpg/>. The TTN provides information and technology exchange in various areas of air pollution control.

*C. Judicial Review*

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available only by filing a petition for review in the United States