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Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments and submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

## XVI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Radiological Devices Panel, Transcript, pp. 142–156, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=659>, May 23, 2006.

2. Pisano, E., Gatsonis, C., Hendrick, E., et al., “Digital Mammographic Imaging Screening Trial (DMIST) Investigators Group,” “Diagnostic Performance of Digital Versus Film Mammography for Breast-Cancer Screening,” *New England Journal of Medicine*, 353: 1773–1783, 2005.

3. Yaffe, M., Bloomquist, A., Mawdsley, G., et al., “Quality Control for Digital Mammography: Part II Recommendations From the ACRIN DMIST Trial,” *Medical Physics*, 33(3): 737–752, 2006.

4. Thomas, J., Chakrabarti, K., Kaczmarek, R., et al., “Contrast Detail Phantom Scoring Methodology,” *Medical Physics*, 32(3), 807, 2005.

5. Device recalls are described in FDA’s briefing information, slide number 12, available at [http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4219b1\\_04\\_draft%20FDA%20presentation.pdf](http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4219b1_04_draft%20FDA%20presentation.pdf).

## List of Subjects in 21 CFR Part 892

Medical device, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 892 be amended as follows:

## PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR part 892 continues to read as follows:

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

2. Section 892.1 is amended by adding paragraph (e) to read as follows:

### § 892.1 Scope.

\* \* \* \* \*

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

3. Section 892.1715 is added to subpart B to read as follows:

### § 892.1715 Full field digital mammography system.

(a) *Identification.* A full field digital mammography system is a device intended to produce full field digital x-ray images of the breast. This generic type of device may include one or more of the following: Digital mammography software, full field digital image receptor, acquisition workstation, and signal analysis programs.

(b) *Classification.* Class II (special controls). The special control for the device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Full Field Digital Mammography System.” See 892.1(e) for the availability of this guidance document.

Dated: May 21, 2008.

**Daniel G. Schultz,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. E8–12120 Filed 5–29–08; 8:45 am]

**BILLING CODE 4160–01–S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R03–OAR–2007–0449; FRL–8574–2]

### Approval and Promulgation of Air Quality Implementation Plans; Delaware; Reasonably Available Control Technology Under the 8-Hour Ozone National Ambient Air Quality Standard

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Delaware. This SIP revision pertains to the requirements in meeting the reasonably available control technology (RACT) under the 8-hour ozone national ambient air quality standard (NAAQS). These requirements are based on: Certification that previously adopted RACT controls in Delaware’s SIP that were approved by EPA under the 1-hour ozone NAAQS are based on the currently available technically and economically feasible controls, and that they continue to represent RACT for the 8-hour implementation purposes; the adoption of new or more stringent

regulations that represent RACT control levels; and a negative declaration that certain categories of sources do not exist in Delaware. This action is being taken under the Clean Air Act (CAA).

**DATES:** Written comments must be received on or before June 30, 2008.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA–R03–OAR–2007–0449 by one of the following methods:

A. *http://www.regulations.gov.* Follow the online instructions for submitting comments.

B. *E-mail:* [fernandez.cristina@epa.gov](mailto:fernandez.cristina@epa.gov).

C. *Mail:* EPA–R03–OAR–2007–0449, Cristina Fernandez, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *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 Docket ID No. EPA–R03–OAR–2007–0449. 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.regulations.gov>, 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 <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is 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 <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 <http://www.regulations.gov> index. 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 <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 Delaware Department of Natural Resources and Environmental Control, 89 Kings Highway, P.O. Box 1401, Dover, Delaware 19901.

**FOR FURTHER INFORMATION CONTACT:** Rose Quinto, (215) 814-2182, or by e-mail at [quinto.rose@epa.gov](mailto:quinto.rose@epa.gov).

**SUPPLEMENTARY INFORMATION:** On October 2, 2006, the Delaware Department of Natural Resources and Environmental Control (DNREC) submitted a revision to its SIP that addresses the requirements of RACT under the 8-hour ozone NAAQS. On October 5, 2006, DNREC submitted a supplement to this SIP revision.

## I. Background

Ozone is formed in the atmosphere by photochemical reactions between volatile organic compounds (VOC), oxides of nitrogen (NO<sub>x</sub>) and carbon monoxide (CO) in the presence of sunlight. In order to reduce ozone concentrations in the ambient air, the CAA requires all nonattainment areas to apply control on VOC/NO<sub>x</sub> emission sources to achieve emission reductions. Among effective control measures, RACT controls are a major group for reducing VOC and NO<sub>x</sub> emissions from stationary sources.

RACT is defined as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility (44 FR 53761 at 53762, September 17, 1979). Section 182 of the CAA sets forth

two separate RACT requirements for ozone nonattainment areas. The first requirement, contained in section 182(a)(2)(A) of the CAA, and referred to as RACT fix-up requires the correction of RACT rules for which EPA identified deficiencies before the CAA was amended in 1990. Delaware has no deficiencies to correct under this section of the CAA. The second requirement, set forth in section 182(b)(2) of the CAA, applies to moderate (or worse) ozone nonattainment areas as well as to marginal and attainment areas in ozone transport regions (OTRs) established pursuant to section 184 of the CAA, and requires these areas to implement RACT controls on all major VOC and NO<sub>x</sub> emission sources and on all sources and source categories covered by a control technique guideline (CTG) issued by EPA.

Under the 1-hour ozone NAAQS, Kent and New Castle Counties in Delaware were designated part of a severe ozone nonattainment area, and Sussex County was designated as a marginal ozone nonattainment area located in an OTR. Therefore, all three counties were subject to RACT requirements under the 1-hour ozone standard. Since the early 1990s, Delaware implemented numerous RACT controls throughout the State to meet the CAA RACT requirements. These RACT controls were promulgated in the Delaware Air Pollution Control Regulation No. 24 for VOC sources and Regulation No. 12 for NO<sub>x</sub> sources.

Under the 8-hour ozone NAAQS, the entire State of Delaware (Kent, New Castle and Sussex Counties) is a part of the Philadelphia moderate nonattainment area, and is therefore subject to the CAA requirements. Delaware is required to submit to EPA a SIP revision that addresses how Delaware meets the RACT requirements under the 8-hour ozone standard. The entire State of Delaware is also part of the OTR established under section 184 of the CAA.

EPA requires under the 8-hour ozone NAAQS that states meet the CAA RACT requirements, either through a certification that previously adopted RACT controls in their SIP revisions approved by EPA under the 1-hour ozone NAAQS represent adequate RACT control levels for 8-hour attainment purposes, or through the

adoption of new or more stringent regulations that represent RACT control levels. A certification must be accompanied by appropriate supporting information such as consideration of information received during the public comment period and consideration of new data. This information may supplement existing RACT guidance documents that were developed for the 1-hour standard, such that the State's SIP accurately reflects RACTs for the 8-hour ozone standard based on the current availability of technically and economically feasible controls. Adoption of new RACT regulations will occur when states have new stationary sources not covered by existing RACT regulations, or when new data or technical information indicates that a previously adopted RACT measure does not represent a newly available RACT control level. Another 8-hour ozone NAAQS requirement for RACT is to submit a negative declaration that there are no CTG or non-CTG major sources of VOC and NO<sub>x</sub> emissions within Delaware.

## II. Summary of SIP Revision

Delaware's SIP revision contains the requirements of RACT set forth by the CAA under the 8-hour ozone NAAQS. Delaware's SIP revision satisfies the 8-hour RACT requirements through (1) certification that previously adopted RACT controls in Delaware's SIP that were approved by EPA under the 1-hour ozone NAAQS are based on the currently available technically and economically feasible controls, and continues to represent RACT for the 8-hour implementation purposes; (2) the adoption of new or more stringent regulations that represent RACT control levels; and (3) a negative declaration that certain CTG or non-CTG major sources of VOC and NO<sub>x</sub> sources do not exist in Delaware.

### VOC RACT Controls

Delaware Air Pollution Control Regulation No. 1124 (formerly Regulation 24) contains Delaware's VOC RACT controls that were implemented and approved in the Delaware SIP under the 1-hour ozone NAAQS.

Table 1 lists Delaware's VOC RACT controls.

TABLE 1.—DELAWARE'S VOC RACT CONTROLS

Regulation 1124	Control of volatile organic compound emissions (formerly Regulation 24)			
	Title of regulation	State effective date	Federal Register date	Citation
Section 10	Aerospace Coatings .....	02/11/03	03/24/04	69 FR 13737.
Section 11	Mobile Equipment Repair and Refinishing .....	11/11/01	11/22/02	67 FR 70315.
Section 12	Surface Coating of Plastics Parts .....	11/29/94	01/26/96	61 FR 2419.
Section 13	Automobile and Light-Duty Truck Coating Operations .....	01/11/93	05/03/95	60 FR 21707.
Section 14	Can Coating .....	01/11/93	05/03/95	60 FR 21707.
Section 15	Coil Coating .....	01/11/93	05/03/95	60 FR 21707.
Section 16	Paper Coating .....	01/11/93	05/03/95	60 FR 21707.
Section 17	Fabric Coating .....	01/11/93	05/03/95	60 FR 21707.
Section 18	Vinyl Coating .....	01/11/93	05/03/95	60 FR 21707.
Section 19	Coating of Metal Furniture .....	01/11/93	05/03/95	60 FR 21707.
Section 20	Coating of Large Appliances .....	01/11/93	05/03/95	60 FR 21707.
Section 21	Coating of Magnet Wire .....	11/29/94	01/26/96	61 FR 2419.
Section 22	Coating of Miscellaneous Metal Parts .....	01/11/93	05/03/95	60 FR 21707.
Section 23	Coating of Flat Wood Paneling .....	01/11/93	05/03/95	60 FR 21707.
Section 24	Bulk Gasoline Plants .....	01/11/93	05/03/95	60 FR 21707.
Section 25	Bulk Gasoline Terminals .....	11/29/92	01/26/96	61 FR 2419.
Section 26	Gasoline Dispensing Facility—Stage I Vapor Recovery .....	01/11/02	11/14/03	68 FR 64520.
Section 27	Gasoline Tank Trucks .....	01/11/93	05/03/95	60 FR 21707.
Section 28	Petroleum Refinery Sources .....	01/11/93	05/03/95	60 FR 21707.
Section 29	Leaks from Petroleum Refinery Equipment .....	11/29/94	01/26/96	61 FR 2419.
Section 30	Petroleum Liquid Storage in External Floating Roof Tanks .....	11/29/94	01/26/96	61 FR 2419.
Section 31	Petroleum Liquid Storage in Fixed Roof Tanks .....	11/29/94	01/26/96	61 FR 2419.
Section 32	Leaks from Natural Gas/Gasoline Processing Equipment .....	11/29/94	01/26/96	61 FR 2419.
Section 33	Solvent Metal Cleaning and Drying .....	11/11/01	11/22/02	67 FR 70315.
Section 34	Cutback and Emulsified Asphalt .....	01/11/93	05/03/95	60 FR 21707.
Section 35	Manufacture of Synthesized Pharmaceutical Products .....	11/29/94	01/26/96	61 FR 2419.
Section 36	Stage II Vapor Recovery .....	01/11/02	11/14/03	68 FR 64540.
Section 37	Graphic Arts Systems .....	11/29/94	01/26/96	61 FR 2419.
Section 38	Petroleum Solvent Dry Cleaners .....	01/11/93	05/03/95	60 FR 21707.
Section 39	Perchloroethylene Dry Cleaning .....	01/11/93	05/03/95	60 FR 21707.
Section 40	Leaks from Synthetic Organic Chemical, Polymer, and Resin Manufacturing Equipment.	01/11/93	05/03/95	60 FR 21707.
Section 41	Manufacture of High-Density Polyethylene, Polypropylene and Polystyrene Resins.	01/11/93	05/03/95	60 FR 21707.
Section 42	Air Oxidation Processes in the Synthetic Organic Chemical Manufacturing Industry.	01/11/93	05/03/95	60 FR 21707.
Section 43	Bulk Gasoline Marine Tank Vessel Loading Facilities .....	11/29/94	01/26/96	61 FR 2419.
Section 44	Batch Processing Operations .....	11/29/94	01/26/96	61 FR 2419.
Section 45	Industrial Cleaning Solvents .....	11/29/94	01/26/96	61 FR 2419.
Section 47	Offset Lithographic Printing .....	11/29/94	01/26/96	61 FR 2419.
Section 48	Reactor Processes and Distillation Operations in the Synthetic Organic Chemical Manufacturing Industry.	11/29/94	01/26/96	61 FR 2419.
Section 49	Control of Volatile Organic Compound Emissions from Volatile Organic Liquid Storage Vessels.	11/29/94	01/26/96	61 FR 2419.
Section 50	Other Facilities that Emit Volatile Organic Compounds (VOCs) .....	11/29/94	01/26/96	61 FR 2419.

Delaware adopted a new VOC RACT control for lightering operations (Section 46) and submitted it to EPA as a SIP revision. EPA approved this VOC RACT on September 13, 2007 (72 FR 52285) with an effective date of October 15, 2007.

Delaware also submitted a negative declaration that the following VOC CTG

or non-CTG major sources do not exist in Delaware: Manufacture of pneumatic rubber tires; wood furniture manufacturing operations; and shipbuilding and ship repair operations (surface coating).

#### *NO<sub>x</sub> RACT Controls*

Delaware Air Pollution Control Regulation No. 12 contains Delaware's NO<sub>x</sub> RACT controls that were implemented and approved into the Delaware SIP under the 1-hour ozone NAAQS.

Table 2 lists Delaware's NO<sub>x</sub> RACT controls.

TABLE 2.—DELAWARE'S NO<sub>x</sub> RACT CONTROLS

Regulation 12	Control of nitrogen oxide emissions		
Source group	State effective date	Federal Register date	Citation
Fuel burning equipment with an input capacity of 100 mmBTU/hour or greater .....	11/24/93	06/14/01	66 FR 32231.
Fuel burning equipment with an input capacity of 50 mmBTU/hour or greater and less than 100 mmBTU/hour.	11/24/93	06/14/01	66 FR 32231.
Fuel burning equipment with an input capacity of less than 50 mmBTU/hour .....	11/24/93	06/14/01	66 FR 32231.
Alternative requirement for fuel burning equipment—Seasonal fuel switching (April 1 through October 31) to a low NO <sub>x</sub> emitting fuel.	11/24/93	06/14/01	66 FR 32231.
Gas turbines .....	11/24/93	06/14/01	66 FR 32231.
Stationary internal combustion engines .....	11/24/93	06/14/01	66 FR 32231.
Fuel burning equipment used exclusively for providing residential comfort heating and hot water.	11/24/93	06/14/01	66 FR 32231.
Incinerator or thermal/catalytic oxidizer constructed before November 15, 1992, and used primarily for the control of air pollution.	11/24/93	06/14/01	66 FR 32231.
Fuel burning equipment with rated heat capacity of less than 15 mmBTU/hour .....	11/24/93	06/14/01	66 FR 32231.
Stationary internal combustion engine with a rated capacity of less than 450 hp of output power.	11/24/93	06/14/01	66 FR 32231.
Any source operating during the month of November to the end of March and operating with a capacity factor of five percent or less from April 1 to October 31.	11/24/93	06/14/01	66 FR 32231.
Any fuel burning equipment, gas turbine, or internal combustion engine with an annual capacity factor of less than five percent.	11/24/93	06/14/01	66 FR 32231.
Case-by-case RACT determination .....	11/24/93	06/14/01	66 FR 32231.

Delaware submitted a negative declaration that the following CTG or non-CTG major sources of NO<sub>x</sub> emissions do not exist in Delaware: cement kilns and stationary internal combustion engines.

### III. Proposed Action

EPA is proposing to approve the Delaware SIP revision that addresses the requirements of RACT under the 8-hour ozone NAAQS. Delaware submitted this SIP revision on October 2, 2006 and a supplement submittal on October 5, 2006. This SIP revision is based on a combination of (1) certification that previously adopted RACT controls in Delaware's SIP that were approved by EPA under the 1-hour ozone NAAQS are based on the currently available technically and economically feasible controls, and that they continue to represent RACT for the 8-hour implementation purposes; (2) the adoption of new or more stringent regulations that represent RACT control levels; and (3) the negative declaration that there are no CTG or non-CTG major sources of VOC and NO<sub>x</sub> emissions within Delaware. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

### IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a).

Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- 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 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 proposed rule, pertaining to the Delaware RACT under the 8-hour ozone NAAQS, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP 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.

### List of Subjects in 40 CFR Part 52

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

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

Dated: May 21, 2008.

**William T. Wisniewski,**

*Acting Regional Administrator, Region III.*  
[FR Doc. E8-12122 Filed 5-29-08; 8:45 am]

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