

summoned an exempt member for jury duty.

Dated: October 3, 2006.

C.R. Choate,

*Alternate OSD Federal Register Liaison
Officer, Department of Defense.*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 12

[EPA-R03-OAR-2006-0638; FRL-8229-6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of Volatile Organic Compounds From Medical Device Manufacturing

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan revision submitted by the Maryland Department of the Environment. This revision pertains to the control of volatile organic compounds from medical device manufacturing. This action is being taken under the Clean Air Act (CAA or the Act).

DATES: Written comments must be received on or before November 9, 2006.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2006-0638 by one of the following methods:

A. www.regulations.gov. Follow the on-line instructions for submitting comments.

B. E-mail: morris.makeba@epa.gov.

C. Mail: EPA-R03-OAR-2006-0638, Makeba Morris, 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-2006-0638. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at 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 www.regulations.gov or e-mail. The 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 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 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 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 Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT:

Helene Drago, (215) 814-5796, or by e-mail at drago.helene@epa.gov.

SUPPLEMENTARY INFORMATION: On May 31, 2006 and July 5, 2006, the Maryland Department of the Environment (MDE) submitted a revision (#06-04) to its State Implementation Plan (SIP) to establish Reasonably Available Control Technology (RACT) requirements for the manufacturing of hypodermic products, syringes, catheters, blood handling and other medical devices. The revision applies to any medical device manufacturing installation that emits, or has the potential to emit, 100

pounds or more per day of volatile organic carbon (VOC). The revisions add Regulation .31 under the Code of Maryland Regulations (COMAR) 26.11.19, Volatile Organic Compounds from Specific Processes.

I. Background

Medical device manufacturing includes production of hypodermic products, catheters, syringes, blood collection, processing, storage and transfusion products. Although the products are small in size, the large volume of pieces manufactured generates significant VOC emissions. The majority of VOC emissions from manufacturing of medical devices comes from bonding of components, coating and cleaning operations. First and foremost, medical device manufacturers are required to comply with the requirements of Food, Drug and Cosmetics Act and the regulations promulgated by Food and Drug Administration (FDA). Medical device manufacturing operations are not covered under any specific Federal environmental regulations.

Under Maryland's regulations found at COMAR 26.11.19, Control of Volatile Organic Compounds from Specific Processes, a facility that has the potential to emit more than 25 tons a year of VOC emissions is subject to the RACT requirements under COMAR 26.11.19.02. The purpose of this regulation is to establish a RACT requirement specific to the medical device manufacturers engaged in the production of hypodermic products, syringes, catheters, blood handling and other medical devices.

II. Summary of SIP Revision

The regulation applies to a person who owns or operates a medical device manufacturing installation that emits or has the potential to emit, 100 pounds or more per day of VOC emissions. Medical device manufacturing operations are also subject to the compliance, recordkeeping and general requirements under COMAR 26.11.19.02 and equipment leak requirements under COMAR 26.11.19.16. The regulations establish control requirements for three main VOC emitting operations: (1) Solvent bonding, (2) biopassive coating, and (3) steel cannula coating. For solvent bonding operations, appropriately designed VOC impermeable covers on dip pots are required. Due to the evolving nature of the process, the State may, if necessary, require participation in an evaluation of new or innovative designs or VOC material substitutions. Biopassive coating operation is required

to be carried out using an enclosed system for fully assembled medical devices. Individual components can only be coated if an approval is granted based on technical and economic justification. Solvents used in steel cannula coating must be chilled to 50 °F or less using a solvent chiller system to minimize VOC emissions. The regulations provide flexibility for companies to achieve an equivalent level of control through an alternative method.

At this time, there is only one affected source located in Cecil County, Maryland. The company manufactures syringes and a range of cardiovascular products and devices such as catheters, filters, pumps and heat exchangers. It is estimated that as a result of this regulation, approximately 1.2 to 1.7 tons of VOC emissions per year will be reduced.

III. Proposed Action

EPA has reviewed the material submitted by Maryland on May 31, 2006 and July 5, 2006. EPA is proposing to approve the Maryland SIP revision for RACT requirements for the manufacturing of hypodermic products, syringes, catheters, blood handling and other medical devices. 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 Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed 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 proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed 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 proposes to approve 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

(Pub. L. 104–4). This proposed rule also does 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), nor will it 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), because it merely proposes to approve 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 proposed rule also is not subject to Executive Order 13045 (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. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the “Attorney General’s Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings” issued under the executive order. This proposed rule for RACT requirements for the manufacturing of hypodermic products, syringes, catheters, blood handling and other medical devices does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

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

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

Dated: September 28, 2006.

William T. Wisniewski,

Acting Regional Administrator, Region III.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R03–OAR–2006–0353; FRL–8229–5]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Redesignation of the Kent and Queen Anne’s 8-Hour Ozone Nonattainment Area to Attainment and Approval of the Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a redesignation request and a State Implementation Plan (SIP) revision for the Kent and Queen Anne’s, MD (herein referred to as the “Kent and Queen Anne’s area”) area from nonattainment to attainment of the 8-hour ozone National Ambient Air Quality Standard (NAAQS). The Maryland Department of the Environment (MDE) is requesting that Kent and Queen Anne’s County, Maryland (herein known as “Kent and Queen Anne’s area”) be redesignated as attainment for the 8-hour ozone NAAQS. The Kent and Queen Anne’s 8-hour ozone nonattainment area is comprised of two counties (Kent and Queen Anne’s Counties, Maryland). EPA is proposing to approve the ozone redesignation request for the Kent and Queen Anne’s area. In conjunction with its redesignation request, the MDE submitted a SIP revision consisting of a maintenance plan for Kent and Queen Anne’s that provides for continued attainment of the 8-hour ozone NAAQS for the next 12 years. EPA is proposing to make a determination that Kent and Queen Anne’s has attained the 8-hour ozone NAAQS based upon three years of complete, quality-assured ambient air quality ozone monitoring data for 2003–2005. EPA’s proposed approval of the 8-hour ozone redesignation request is based on its determination that Kent and Queen Anne’s has met the criteria for redesignation to attainment specified in the Clean Air Act (CAA). EPA is