conference on the issues involved. In January 1995, FDA and the National Institutes of Health cosponsored a public forum on informed consent in clinical research conducted in emergency circumstances. In the **Federal Register** of September 21, 1995 (60 FR 49086), FDA proposed to amend its regulations to provide an exception to informed consent for research of emergency treatment for persons with acute and unpredictable life-threatening illnesses. After analysis of over 90 comments, in the **Federal Register** October 2, 1996 (61 FR 51498), FDA published the final rule (§ 50.24) that is the subject of this public meeting. The Department of Health and Human Services simultaneously published (61 FR 51531, October 2, 1996) a functionally equivalent waiver of its human subject protection regulations (45 CFR part 46).

The exception to the normal requirements for obtaining informed consent (61 FR 51531) is narrow in scope and available for research conducted in emergency circumstances on treatments for life-threatening conditions. The exception requires additional protections beyond those provided for human research subjects in other research.

While § 50.24 provides specific requirements for use of the exception to informed consent, FDA recognized that local conditions vary throughout the Nation, and placed considerable discretion and responsibility in the IRB's that will review proposed studies, the clinical investigators who will conduct the studies, and the sponsors who will initiate the studies and utilize the results. Questions have arisen as to the appropriate methods to satisfy the regulatory requirements imposed for use of the exception.

At the public meeting, participants will examine the methods of providing the additional protections required when utilizing the exception to informed consent. Presentations and discussions will address the specific measures required. Participants will be provided opportunities to share their views and information regarding protocol design, study conduct, and experiences of clinical research conducted or planned under the exception to informed consent.

On September 29, 1997, the meeting will open with discussions describing how the final rule was developed, what FDA expects to receive from sponsors, and how to determine whether clinical equipoise exists between standard therapy and an investigational procedure. Representatives of a study sponsor will describe how that study has been implemented at multiple study sites. A panel of experts will discuss issues related to consultation with representatives of the community where the research will be conducted and from which subjects will be drawn, if different, and disclosure of the research to the community. A session of open discussion will provide an opportunity for audience participation. A second panel of experts will discuss issues related to procedures for seeking consent from a subject's legal representative, and documenting the attempts to obtain consent. A session of open discussion will follow.

On September 30, 1997, the meeting will open with presentations describing the function and operation of data safety monitoring boards that are required for studies under the final rule, as well as the other requirements of the final rule. A representative of a study sponsor will describe the preparation for and coordination of a multi-site study. A panel of experts will discuss the circumstances in which it is appropriate to use the final rule, and how the different parties involved should interact with each other to produce a useful study. A session of open discussion will follow and then the meeting will conclude.

All sessions of the meeting are open to the public; however, open seating is limited to 300. Those persons interested in attending should submit registration information, including name, organization name, address, telephone and fax numbers to the contact listed in this document. There is no registration fee for this public meeting, but advanced registration is recommended, as preregistrants will have preference if seating capacity is exceeded. Interested parties are encouraged to register early because space is limited.

Interested persons may, on or before October 31, 1997, submit to the Dockets Management Branch (address above) written comments regarding the workshop. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Additional information as well as a registration form is also available at FDA's website at http.//www.fda.gov.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–23123 Filed 8–29–97; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD040–3018a; FRL–5881–6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of Volatile Organic Compound Emissions From Sheet-Fed and Web Lithographic Printing and Paper Coatings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving the State Implementation Plan (SIP) revisions submitted by the State of Maryland on July 11, 1995. These revisions establish volatile organic compound (VOC) emission reduction requirements for sheet-fed and web lithographic printing operations, and paper, fabric, vinyl, and other plastic coating operations throughout the State of Maryland under COMAR 26.11.19 Volatile Organic Compounds from Specific Processes. EPA is also approving the administrative changes to Maryland's regulations for VOC emissions from specific processes. The intended effect of this action is to approve these provisions into the Maryland SIP, in accordance with the SIP submittal and revision provisions of the Clean Air Act (the Act). This action is being taken under section 110 of the Act.

EFFECTIVE DATE: This final rule is effective November 3, 1997 unless by October 2, 1997, adverse or critical comments are received. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments may be mailed to David L. Arnold, Chief, Ozone/CO and Mobile Sources Section, Mailcode 3AT21, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107 and the Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland 21224.

FOR FURTHER INFORMATION CONTACT: Carolyn M. Donahue, (215) 566–2095, at the EPA Region III office address listed above, or via e-mail at donahue.carolyn@epamail.epa.gov. While information may be requested via e-mail, comments must be submitted in writing to the above Region III address.

SUPPLEMENTARY INFORMATION: On July 11, 1995, the Maryland Department of the Environment (MDE) submitted new and revised regulations to EPA as State Implementation Plan (SIP) revisions. These regulations control emissions of VOCs throughout the State. MDE submitted these SIP revision requests pursuant to the rate-of-progress (ROP) requirements of section 182 of the Act. Specifically, Maryland has adopted VOC control measures for lithographic printing operations and paper coating operations. A more detailed analysis of Maryland's submittal is contained in the Technical Support Document for this action.

Background

Section 182(b)(1) of the Act requires states with ozone nonattainment areas classified as moderate or above to reduce VOC emissions 15% from 1990 baseline levels. States were required to achieve the 15% VOC emission reduction by 1996. This ROP requirement, known as the 15% plan, was due to EPA as a SIP revision by November 15, 1993.

In Maryland, 15% plans were required for the Baltimore severe ozone nonattainment area, the Maryland portion of the Philadelphia severe ozone nonattainment area, and the Maryland portion of the Metropolitan Washington, DC serious ozone nonattainment area. Maryland submitted the required 15% plans to EPA as SIP revisions on July 12, 1995. In these 15% plans, Maryland takes credit for the emission reductions achieved through the VOC regulations that Maryland submitted as SIP revisions on July 11, 1995. These regulations must be approved into Maryland's SIP before the 15% plans can be approved.

Summary of SIP Revisions

State Submittal: COMAR 26.11.19.11 Control of VOC Emissions From Sheet-Fed and Web Lithographic Printing

This revision establishes standards for lithographic printing operations from sheet-fed and web printers. EPA approved subsections A, B, and C of this regulation (59 FR 60908, November 29, 1994) into the Maryland SIP. On October 18, 1993, Maryland withdrew sections D and E of the lithographic printing regulation from federal consideration, but resubmitted the regulation with two sets of amendments on July 11, 1995. The first set of amendments was adopted by the state of Maryland on July 24, 1991 and effective August 19, 1991. The second set of amendments was adopted by the State on May 5, 1995 and effective on June 5, 1995.

General Provisions

This SIP revision applies to regulations .01, .07, .10, and .11 under COMAR 26.11.19 Volatile Organic Compounds from Specific Processes. Administrative revisions to sections .01, .07, and .10, such as recodifying term definitions, result from revisions to section .11.

The lithographic printing regulation applies to a person who owns or operates a lithographic web printing press in any facility where the actual VOC emissions from all lithographic web printing presses exceed 100 pounds per day, or to a person who owns or operates a sheet-fed lithographic printing press of a cylinder width 18 inches or greater. The title of this regulation was amended to ''Lithographic Printing'' from ''Other Miscellaneous Printing and Coating Processes.'' This regulation does not apply to printing on fabric, metal, or plastic.

Requirements for Sheet-Fed Printers

A person may not use any sheet-fed letter or lithographic printing press with a cylinder width of 18 inches or greater unless the fountain solution is refrigerated to maintain a temperature less than 55° F (if isopropyl alcohol is used). Also, a temperature indicator must be installed to monitor fountain solution temperature if the solution is refrigerated, and the fountain solution must contain less than 8.5 percent isopropyl alcohol by weight.

Requirements for Lithographic Web Printers

A person operating a lithographic web printing press shall operate the press only if the dryer exhaust is ducted to a control device that is constructed, operated and maintained to achieve an overall control efficiency of 90 percent or more. Also, isopropyl alcohol must not be used in the fountain solution.

Requirements for all Lithographic Printing Presses

A person using VOC-containing materials to clean printing presses is required to store all waste material containing VOC in closed containers, maintain lids on VOC-containing cleanup materials when not in use, and participate, upon request by MDE, in the evaluation of non-VOC and low-VOC cleaning materials when these materials have the potential to be substitutes for currently used materials. Also, good operating practices for persons who clean printing equipment must be established in writing and made available upon request from MDE.

EPA Evaluation: These revisions, which regulate VOC emissions from lithographic printing operations, will result in significant enforceable VOC emission reductions. These reductions are needed for Maryland's 15% plans. EPA has determined that Maryland's regulation, COMAR 26.11.19.11, Lithographic Printing, as well as the administrative changes to COMAR 26.11.19.01, .07 and .10, are approvable as SIP revisions.

State Submittal: Revision to COMAR 26.11.19.07 Control of VOC Emissions From Paper, Fabric, Vinyl, and Other Plastic Parts Coating

This regulation establishes standards for the application of coating materials on paper, fabric, vinyl, and other plastic substances. EPA has previously approved revisions to this regulation on September 7, 1994 (59 FR 46180) and November 29, 1994 (59 FR 60908).

Requirements for Paper, Fabric and Vinyl Coating

This regulation, COMAR 26.11.19.07.B, applies to a person who performs web or sheet-fed paper, fabric or vinyl coating at a facility where the total facility VOC emissions are more than 50 pounds per day.

Requirements for Plastic Parts Coating

Also, a person may not emit more than 20 pounds per day of VOC from any plastic parts coating installation, unless the coating contains less than 3 pounds of VOC per gallon of coating minus water. This revision adds section E to COMAR 26.11.19.07 Paper, Fabric, Vinyl and Other Plastic Parts Coating.

EPA Evaluation: These revisions, which regulate VOC emissions from paper, fabric, vinyl and other plastic parts coating operations, will result in significant enforceable VOC emission reductions. These reductions are needed for Maryland's 15% plans. EPA has determined that the revisions to Maryland's regulation COMAR 26.11.19.07 are approvable as SIP revisions.

EPA is approving these SIP revisions without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the SIP revisions should adverse or critical comments be filed. This action will be effective November 3, 1997 unless, within 30 days of publication, adverse or critical comments are received.

If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective on November 3, 1997.

Final Action

EPA is approving revisions to the Maryland SIP to establish VOC control requirements for sheet-fed and web lithographic printing operations, and paper, fabric, vinyl and other plastic coating operations. These regulations achieve fully enforceable VOC emission reductions.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Regional Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action proposed/promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

Under section 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action to approve Maryland's VOC control regulations for sheet-fed and web lithographic printing and paper coating must be filed in the United States Court of Appeals for the appropriate circuit by November 3, 1997. 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 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, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements.

Dated: August 15, 1997.

Thomas Voltaggio,

Acting Regional Administrator, Region III.

40 CFR part 52, subpart V of chapter I, title 40 is amended as follows:

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401–7671q.

Subpart V—Maryland

2. Section 52.1070 is amended by adding paragraphs (c) (126) and (127) to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

(126) Revisions to the Maryland State Implementation Plan submitted on July 11, 1995 by the Maryland Department of the Environment:

(i) Incorporation by reference.

(A) Letter of July 11, 1995 from the Maryland Department of the Environment transmitting additions and deletions to Maryland's State Implementation Plan, pertaining to volatile organic compound regulations in Maryland's air quality regulations, Code of Maryland Administrative Regulations (COMAR) 26.11.

(B) Revision to COMAR 26.11.19.11 Control of VOC Emissions from Sheet-Fed and Web Lithographic Printing, adopted by the Secretary of the Environment on May 5, 1995, and effective on June 5, 1995, including the following:

(*1*) Deletion of COMAR 26.11.19.11 title, ''Other Miscellaneous Printing and Coating Processes'' and addition of new title, ''Lithographic Printing.''

(*2*) Deletion of COMAR 26.11.19.11.A(4), definition for the term ''plastic parts coating.''

(*3*) Deletion of COMAR 26.11.19.11.B(1), referencing plastic parts coating.

(*4*) Addition of new COMAR 26.11.19.11.B(1) & (3) through (6) Applicability.

(*5*) Deletion of COMAR 26.11.19.11.C Emission Standards for Plastic Coating.

(*6*) Addition of new COMAR 26.11.19.11.C Requirements for Sheet-Fed Letter or Lithographic Printing.

(*7*) Addition of new COMAR 26.11.19.11.D Requirements for Lithographic Web Printing.

(*8*) Addition of new COMAR 26.11.19.11.E Requirements for Cleaning Printing Equipment.

(*9*) Deletion of COMAR 26.11.19.10 title, ''Graphic Arts'' and addition of new title, ''Flexographic and Rotogravure Printing.''

(*10*) Deletion of COMAR 26.11.19.10.A(4), definition for the term ''web printing.''

(*11*) Addition of COMAR 26.11.19.01.B(8), definition for the term ''web printing.''

(ii) Additional Material.

(A) Remainder of July 11, 1995 Maryland State submittal pertaining to COMAR 26.11.19.11 Control of VOC Emissions from Sheet-Fed and Web Lithographic Printing.

(127) Revisions to the Maryland State Implementation Plan submitted on July 11, 1995 by the Maryland Department of the Environment:

(i) Incorporation by reference.

(A) Letter of July 11, 1995 from the Maryland Department of the Environment transmitting additions to Maryland's State Implementation Plan, pertaining to volatile organic compound regulations in Maryland's air quality regulations, Code of Maryland Administrative Regulations (COMAR) 26.11.

(B) Revision to COMAR 26.11.19.07 Control of VOC Emissions from Paper Coating, adopted by the Secretary of the Environment on May 5, 1995, and effective on June 5, 1995, including the following:

(*1*) Addition of COMAR 26.11.19.07.A(2–1), definition for the term ''plastic parts coating.''

(*2*) Addition of COMAR 26.11.19.07.B(1), referencing paper, fabric and vinyl coating.

(*3*) Addition of COMAR 26.11.19.07.E Emission Standards for Plastic Coating.

(ii) Additional Material.

(A) Remainder of July 11, 1995 Maryland State submittal pertaining to COMAR 26.11.19.07 Control of VOC Emissions from Paper Coating.

[FR Doc. 97–23030 Filed 8–29–97; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–5883–4]

Approval and Promulgation of Air Quality Implementation Plans; Rhode Island; Reasonably Available Control Technology for Nitrogen Oxides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of Rhode Island. This revision establishes and requires Reasonably Available Control Technology (RACT) at stationary sources of nitrogen oxides (NO_X). The intended effect of this action is to approve regulatory provisions and source specific consent agreements which require major stationary sources of NO_X to reduce their emissions statewide in accordance with requirements of the Clean Air Act.

DATES: This action is effective November 3, 1997, unless adverse or critical comments are submitted and received by October 2, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystem Protection (mail code CAA), U.S. Environmental Protection Agency, Region I, JFK Federal Building, Boston, MA 02203–2211. Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA; as well as the Division of Air and Hazardous Materials, Rhode Island Department of Environmental Management, 291 Promenade Street, Providence, RI 02908–5767.

FOR FURTHER INFORMATION CONTACT: Steven A. Rapp, Environmental Engineer, Air Quality Planning Unit (CAQ), U.S. EPA, Region I, JFK Federal Building, Boston, MA 02203–2211; (617) 565–2773; Rapp.Steve@EPAMAIL.EPA.GOV.

SUPPLEMENTARY INFORMATION:

I. Background

The Clean Air Act (CAA) requires that States develop Reasonably Available Control Technology (RACT) regulations for all major stationary sources of nitrogen oxides (NO_X) in areas which have been classified as ''moderate,'' ''serious,'' ''severe,'' and ''extreme'' ozone nonattainment areas, and in all areas of the Ozone Transport Region (OTR). EPA has defined RACT 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 53762; September 17, 1979). This requirement is established by sections 182(b)(2), 182(f), and 184(b) of the CAA.

The CAA NO_X requirements are further described by EPA in a notice entitled ''State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule,'' published November 25, 1992 (57 FR 55620). The November 25, 1992 document (i.e., the NO_X Supplement) should be referred to for more detailed information on NO_X requirements. Additional guidance memoranda which have been released by EPA, such as those included in the ''NO_X Policy Document for the Clean Air Act of 1990,'' (EPA–452/R–96–005, March 1996), should also be referred to for more information on NO_X requirements.

CAA section 182(b)(2) requires States to require implementation of RACT with respect to all major sources of volatile organic compounds (VOC) in moderate ozone nonattainment areas. This RACT requirement also applies to all major sources in ozone nonattainment areas with higher than moderate nonattainment classifications (i.e., serious, severe, and extreme nonattainment areas). See CAA sections 182 (c), (d), and (e). Furthermore, CAA section 182(f) states that, ''[t]he plan provisions required under this subpart for major stationary sources of volatile organic compounds shall also apply to major stationary sources (as defined in section 302 of this title and subsections (c), (d), and (e) of the section) of oxides of nitrogen.'' These sections of the CAA, taken together, require the State of Rhode Island, a serious nonattainment area, to submit a NO_X RACT regulation which covers major sources of NO_X statewide.

Section 302 of the CAA generally defines ''major stationary source'' as a facility or source of air pollution which has the potential to emit 100 tons per year or more of air pollution. This definition applies unless another provision of the CAA explicitly defines major stationary source differently. Therefore, for NO_X, a major source is one with the potential to emit 100 tons per year or more in marginal and