ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52, 60, 264 and 265

[FRL–5803–7]

Project XL Site-specific Rulemaking for Merck & Co., Inc. Stonewall Plant

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to implement a project under the Project XL program for the Merck & Co., Inc. (Merck) Stonewall Plant, in Elkton, Virginia. The terms of the project are defined in a proposed Final Project Agreement (FPA) which is being made available for public review and comment by this document. In addition, EPA is proposing today a site-specific rule, applicable only to the Merck Stonewall Plant, to facilitate implementation of the project. By this document, EPA solicits comment on the proposed rule, the proposed FPA, and the project generally.

This proposed site-specific rule is intended to provide regulatory changes under the Clean Air Act and the Resource Conservation and Recovery Act (RCRA) to implement Merck's XL project, which will result in superior environmental performance and, at the same time, provide Merck with greater operational flexibility. The proposed site-specific rule would change the Clean Air Act requirements which apply to the Merck Stonewall Plant for the prevention of significant deterioration of air quality and certain new source performance standards. EPA also proposes a site-specific rulemaking under RCRA to provide regulatory changes pertaining to air emissions standards to implement this XL project.

DATES: *Comments.* All public comments must be received on or before April 30, 1997. If a public hearing is held, the public comment period will remain open until May 15, 1997.

Public Hearing. A public hearing will be held, if requested, to provide interested persons an opportunity for oral presentation of data, views, or arguments concerning this proposed rule to implement Merck's XL project. If anyone contacts the EPA requesting to speak at a public hearing by April 10, 1997, a public hearing will be held on April 14, 1997. Additional information is provided in the section entitled **ADDRESSES.**

Request to Speak at Hearing. Persons wishing to present oral testimony must contact Ms. Robin Moran at the EPA by April 10, 1997. Additional information is provided in the section entitled **ADDRESSES.**

ADDRESSES: *Comments.* Written comments should be submitted in duplicate to: Ms. Robin Moran, U.S. Environmental Protection Agency, Region III, Air, Radiation & Toxics Division, 841 Chestnut Street (3AT23), Philadelphia, PA, 19107–4431, (215) 566–2064.

Docket. A docket containing supporting information used in developing this proposed rulemaking is available for public inspection and copying at U.S. EPA, Region III, 841 Chestnut Street, Philadelphia, PA, 19107–4431, (215) 566–2064, during normal business hours, and at EPA's Water docket (Docket name ''XL-Merck''); 401 M Street, SW, Washington, DC 20460. For access to the Water docket materials, call (202) 260–3027 between 9:00 a.m. and 3:30 p.m. (Eastern time) for an appointment. A reasonable fee may be charged for copying. A docket is also available for public inspection at the Virginia Department of Environmental Quality, Valley Regional Office, 4411 Early Road, P.O. Box 1129, Harrisonburg, Virginia 22801–1129, (540) 574–7800.

Public Hearing. If a public hearing is held, it will be held at 7:00 p.m. at the following location: Virginia Department of Environmental Quality, Valley Regional Office, 4411 Early Road, P.O. Box 1129, Harrisonburg, Virginia 22801–1129, (540) 574–7800. Persons interested in attending the hearing should notify Ms. Robin Moran, (215) 566–2064, to verify that a hearing will be held.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Moran, U.S. Environmental Protection Agency, Region III, Air, Radiation & Toxics Division, 841 Chestnut Street (3AT23), Philadelphia, PA, 19107–4431, (215) 566–2064.

SUPPLEMENTARY INFORMATION:

Outline of This Document

I. Authority
II. Background
A. Overview of Project XL
B. Overview of the Merck XL Project
1. Introduction
2. Merck XL Project Description
3. Environmental Benefits
4. Stakeholder Involvement
5. Compliance
III. Clean Air Act Requirements
A. Summary of Regulatory Requirements for the Merck XL Project
B. Prevention of Significant Deterioration
1. Requirements of the Clean Air Act
2. Permit Modifications
C. State Implementation Plan Requirements
D. New Source Performance Standards
E. Title V Operating Permit
IV. Resource Conservation and Recovery Act Requirements
V. Additional Information
A. Public Hearing
B. Executive Order 12866
C. Regulatory Flexibility
D. Paperwork Reduction Act
E. Unfunded Mandates Reform Act

I. Authority

This regulation is being proposed under the authority of sections 101(b)(1), 110, 111, 161–169, 169A, and 301(a)(1) of the Clean Air Act, and sections 1006, 2002, 3001–3007, 3010, and 7004 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act, as amended (42 U.S.C. 6905, 6921–6927, 6930, and 6974). EPA has determined that this rulemaking is subject to the provisions of section 307(d) of the Clean Air Act.

II. Background

A. Overview of Project XL

This proposed site-specific rule is designed to implement a project developed under Project XL, an important EPA initiative to allow regulated entities to achieve better environmental results at less cost. Project XL—for ''excellence and leadership''—was announced on March 16, 1995, as a central part of the National Performance Review's and EPA's effort to reinvent environmental protection. See 60 FR 27282 (May 23, 1995). Project XL provides a limited number of private and public regulated entities an opportunity to develop their own pilot projects to provide regulatory flexibility that will result in environmental protection that is superior to what would be achieved through compliance with current and reasonably anticipated future regulations. These efforts are crucial to the Agency's ability to test new regulatory strategies that reduce regulatory burden and promote economic growth while achieving better environmental and public health protection. The Agency intends to evaluate the results of this and other Project XL projects to determine which specific elements of the project, if any, should be more broadly applied to other regulated entities to the benefit of both the economy and the environment.

In Project XL, participants in four categories—facilities, industry sectors, governmental agencies and communities—are offered the flexibility

to develop common sense, cost-effective strategies that will replace or modify specific regulatory requirements, on the condition that they produce and demonstrate superior environmental performance. To participate in Project XL, applicants must develop alternative pollution reduction strategies pursuant to eight criteria—superior environmental performance; cost savings and paperwork reduction; local stakeholder involvement and support; test of an innovative strategy; transferability; feasibility; identification of monitoring, reporting and evaluation methods; and avoidance of shifting risk burden.[1] They must have full support of affected Federal, state and tribal agencies to be selected.

The XL program is intended to allow EPA to experiment with untried, potentially promising regulatory approaches, both to assess whether they provide benefits at the specific facility affected, and whether they should be considered for wider application. Such pilot projects allow EPA to proceed more quickly than would be required to undertake changes on a nationwide basis. As part of this experimentation, EPA may try out approaches or legal interpretations that depart from or are even inconsistent with longstanding Agency practice, so long as those interpretations are within the broad range of discretion enjoyed by the Agency in interpreting statutes that it implements. EPA may also modify rules that represent one of several possible policy approaches within a more general statutory directive, so long as the alternative being used is permissible under the statute.

Adoption of such alternative approaches or interpretations in the context of a given XL project does not, however, signal EPA's willingness to adopt that interpretation as a general matter, or even in the context of other XL projects. It would be inconsistent with the forward-looking nature of these pilot projects to adopt such innovative approaches prematurely on a widespread basis without first finding out whether or not they are viable in practice and successful in the particular projects that embody them. Furthermore, as EPA indicated in announcing the XL program, the Agency expects to adopt only a limited number of carefully selected projects. These pilot projects are not intended to be a means for piecemeal revision of entire programs. Depending on the results in these projects, EPA may or may not be willing to consider adopting the alternative interpretation again, either generally or for other specific facilities.

EPA believes that adopting alternative policy approaches and interpretations, on a limited, site-specific basis and in connection with a carefully selected pilot project, is consistent with the expectations of Congress about EPA's role in implementing the environmental statutes (so long as the Agency acts within the discretion allowed by the statute). Congress' recognition that there is a need for experimentation and research, as well as ongoing re-evaluation of environmental programs, is reflected in a variety of statutory provisions, such as sections 101(b) and 103 of the Clean Air Act. In some cases, as in this XL project, such experimentation requires an alternative regulatory approach that, while permissible under the statute, was not the one adopted by EPA historically or for general purposes.

B. Overview of the Merck XL Project

1. Introduction

This proposed site-specific rule supports a draft permit and Project XL proposed Final Project Agreement (FPA) that have been developed by the Merck XL stakeholder group, namely Merck, EPA, Virginia Department of Environmental Quality (VADEQ), U.S. Department of the Interior (DOI)/ National Park Service (NPS), and community representatives. Several environmental organizations offered valuable input during the stakeholder process, including Southern Environmental Law Center, the Virginia Consortium for Clean Air, and the Natural Resources Defense Council. The proposed FPA and draft permit are available for review in the docket for today's action and also are available on the world wide web at http://www.epa.gov/ProjectXL. The proposed FPA outlines how the project addresses the eight Project XL criteria, in particular how the project will produce, measure, monitor, report, and demonstrate superior environmental benefits. In today's action, the Agency is soliciting comment on proposed site-specific regulatory changes to implement the project. The draft permit is available on the world wide web and in the docket file for today's action; however the draft permit is made available for informational purposes only. The Commonwealth of Virginia is conducting the official comment period for the draft permit, and initiated a public comment period for the draft PSD permit and a proposed variance on January 28, 1997.

EPA also seeks comment on the proposed FPA, which is available on the world wide web and in the docket file for today's action, in light of the criteria outlined in the Agency's May 23, 1995, **Federal Register** notice (60 FR 27282) regarding Regulatory Reinvention (XL) Pilot Projects. Those criteria are: (1) Environmental performance superior to what would be achieved through compliance with current and reasonably anticipated future regulations; (2) cost savings or economic opportunity, and/or decreased paperwork burden; (3) stakeholder support; (4) test of innovative strategies for achieving environmental results; (5) approaches that could be evaluated for future broader application; (6) technical and administrative feasibility; (7) mechanisms for monitoring, reporting, and evaluation; and (8) consistency with Executive Order 12898 on Environmental Justice (avoidance of shifting of risk burden).

2. Merck XL Project Description

The Merck Stonewall Plant is a pharmaceutical manufacturing facility, built in 1941, located near Elkton, Virginia. The facility is located approximately 2 kilometers from the Shenandoah National Park, a Federal Class I area under the Clean Air Act. Currently, the plant employs about 800 people in a range of pharmaceutical manufacturing activities such as fermentation, solvent extraction, organic chemical synthesis, and finishing operations. The facility's products include broad spectrum antibiotics, anti-parasitic drugs for human and animal health, a cholesterol lowering drug, a drug for the treatment of Parkinson's disease, and a new drug for the treatment of human immunodeficiency virus (HIV).

To remain competitive in the worldwide pharmaceutical industry, the Merck Stonewall Plant must respond rapidly to changing market conditions and product demands. To get new pharmaceutical products to market quickly, Merck requires flexible manufacturing operations that can make a broad range of products with the same manufacturing equipment using a wide array of raw materials and solvents. Merck also continually evaluates existing products for yield and process improvements, which results in a need for frequent manufacturing changes. Thus, Merck's facilities often modify environmental permits after a product line is first permitted.

The goal of this XL project is to develop a regulatory structure for the

[1] For more information about the XL criteria, readers should refer to the May 23, 1995 **Federal Register** notice (60 FR 27282) and the December 1, 1995 ''Principles for Development of Project XL Final Project Agreements'' document, both contained in the docket for this action.

Merck Stonewall Plant that both facilitates flexible manufacturing operations and achieves superior environmental performance. The existing preconstruction air permitting regulations that govern modifications at the facility, specifically the Prevention of Significant Deterioration (PSD) permitting regulations and the minor New Source Review (NSR) regulations, require that most changes to Merck's manufacturing processes must be reviewed and approved in advance by the VADEQ. In reviewing permit changes, the VADEQ consults with the Federal Land Manager (FLM) for Shenandoah National Park in accordance with the Memorandum of Understanding between the DOI/NPS and VADEQ. Typically, the more changes that are made or the larger the change, the more time and resources are necessary for permit review. The complexity of the regulations requires a considerable effort by the facility as well as the regulators to prepare and review permit applications for process modifications.

Merck's XL project seeks to replace this complex permitting system with a simpler system of compliance with criteria air pollutant regulations. Through a site-specific rulemaking and enforceable permit conditions, the facility's total emissions of criteria pollutants (except lead)[2] would be capped below the level at which the plant operated over recent years (at approximately 1500 tons per year (TPY)). Within the site-wide total emissions cap, the facility will also be subject to individual pollutant caps (subcaps), established near or below recent actual emission levels, for sulfur dioxide (SO_2), nitrogen oxides (NO_X), and particulate matter with an aerodynamic diameter less than 10 microns (PM_{10}). In addition to accepting these site-wide emissions caps, Merck will modify its existing coal-burning powerhouse to burn natural gas, a cleaner burning fuel that generates substantially fewer emissions than coal. Either propane or number 2 fuel oil would be used as a backup fuel. This multi-million dollar project is not otherwise required by regulations and the boilers do not need to be replaced for other reasons (e.g., operation, age or capacity). The powerhouse conversion would result in an up-front estimated reduction of over 900 TPY of actual criteria air pollutants, primarily SO_2 and NO_X emissions. After this powerhouse conversion, Merck would reduce its total emissions cap by 20 percent, thereby permanently retiring at least 300 TPY of criteria pollutant emissions. Further, Merck also will reduce the pollutant-specific subcaps for SO_2 and NO_X by 25 percent and 10 percent, respectively.

Merck's XL project would be implemented through issuance of a site-wide PSD permit, authorized by this proposed site-specific rulemaking. For the reader's convenience, a copy of the draft PSD permit is included in the docket for today's action. Under the site-specific rule and permit, the Merck Stonewall Plant would be required to maintain its emissions below the total emissions cap, as well as the subcaps for SO_2, NO_X and PM_{10}. Under the site-wide emissions caps, changes or additions to facility operations would no longer need prior approval under PSD or NSR. The subcaps will keep SO_2 and NO_X emissions below recent actual emission levels and PM_{10} emissions will not significantly increase above the recent actual emissions level. The statutory PSD requirements for the VOC and CO emission increases that are possible under the total emissions cap will be satisfied pursuant to this site-specific rule and the PSD permit. So long as the facility complies with the total emissions cap, subcaps, and other permit requirements, it would have the flexibility to make modifications and to operate in a manner that supports Merck's objective to deliver high quality products quickly and efficiently to improve human and animal health without undergoing permit review for each modification.

As an alternative to the current PSD permitting system, the total emissions cap and subcaps will provide an incentive for Merck to identify and promptly implement ongoing emission reductions at the facility to provide operating room under the cap for future modifications and expansions. The XL project also provides an additional incentive for Merck to minimize emissions—a system of ''tiered'' monitoring, recordkeeping and reporting requirements. The draft permit provides that the monitoring, recordkeeping and reporting requirements become more stringent as the facility's actual emissions approach the total emissions cap. This tiered monitoring system provides Merck another built-in incentive to minimize emissions and to find opportunities to implement emission reductions.

3. Environmental Benefits

The Merck XL Project is designed to deliver superior environmental performance while allowing flexible operations at the facility. The site-specific rule and simplified air permit would provide significant benefits to the environment by substantially reducing pollutant emissions near the Shenandoah National Park and the surrounding community.

The Merck Stonewall Plant is located within 2 kilometers of Shenandoah National Park, a Federal Class I area. The facility's proximity to this nationally significant resource highlights the need for serious consideration of opportunities for better protection of the environment. Air quality is of special concern in Shenandoah National Park. Under the Clean Air Act, as amended in 1977, Shenandoah National Park was classified as a mandatory Federal Class I air quality area. Under the PSD program, the Federal Class I designation allows very little additional deterioration of the air quality from established baseline concentrations of certain air pollutants, and none of National Ambient Air Quality Standards (NAAQS) are to be exceeded. The DOI's Assistant Secretary for Fish and Wildlife and Parks is the Federal Land Manager (FLM) charged with direct responsibility to protect the air quality related values (AQRVs) of the Park. In 1990, the FLM for Shenandoah National Park notified the public that visibility is seriously degraded, that sensitive streams and watersheds are being acidified, and that park vegetation is being injured by ozone and sulfur dioxide levels. See 55 FR 38403–38408 (September 18, 1990).

Certain criteria pollutants have been demonstrated to have a significant adverse effect on the environmental quality of the Shenandoah National Park. In particular, SO_2 emissions contribute to visibility problems in the region, and NO_X emissions combine with other chemicals in the atmosphere to form ground-level ozone, which has been determined to cause vegetation damage. Emissions of SO_2 and NO_X also contribute to the formation of acid rain and associated adverse impacts. Merck's powerhouse conversion would achieve an up-front reduction of these pollutants—SO_2 emissions are expected to decrease by 679 TPY (94 percent) and NO_X emissions are expected to decrease by 254 TPY (87 percent), from baseline

[2] The criteria pollutants included in the total emissions cap are sulfur dioxide, nitrogen oxides, carbon monoxide, ozone (using volatile organic compounds as a surrogate), and particulate matter with aerodynamic diameter less than 10 microns. Thus, the total emissions cap includes all existing criteria pollutants except lead. Merck will comply directly with any applicable requirements for the control of lead emissions. Merck currently emits a very low amount of lead emissions (0.3 tons per year), which will be virtually eliminated when the facility converts the coal-burning powerhouse to natural gas. Merck also will comply directly with any applicable requirements for new criteria pollutants which are not included in the total emissions cap.

actual emission levels. After the powerhouse conversion, the total emissions cap and subcaps would ensure a continuing, permanent reduction of these pollutants, as well as provide an ongoing incentive to minimize actual emissions to preserve the operating margin under the caps. Besides the significant reduction in criteria pollutants resulting from the project, the conversion to natural gas also will result in a reduction of about 47 TPY (65 percent) of hazardous air pollutants (HAPs), specifically hydrogen chloride and hydrogen fluoride. These two HAPs are generated by burning coal and are also associated with the formation of acid rain. Reducing emissions of these chemicals also will contribute to efforts to improve air quality in the Shenandoah National Park and the surrounding community.

Although the facility's VOC and CO emissions would be allowed to increase above recent actual emission levels (but within the total emissions cap), there are no identified adverse effects from the maximum allowable levels of these pollutants under the total emissions cap. Moreover, the statutory PSD requirements for VOC and CO will be satisfied pursuant to this proposed site-specific rulemaking and issuance of the PSD permit. Section III.B.1 of the preamble describes the analysis of possible VOC and CO emission increases.

4. Stakeholder Involvement

The Merck XL project enhances the involvement of the community and other stakeholders in understanding and evaluating environmental impacts of the facility. Stakeholders will have an unprecedented opportunity to participate in the ongoing evaluation of the project and to recommend any necessary changes to the project. The draft PSD permit provides that the stakeholders review and evaluate the project at least every five years. If the project signatories (i.e., signatories to the Final Project Agreement, namely EPA, VADEQ, Merck, DOI Federal Land Manager, and Rockingham County Board of Supervisors) give full consent to any necessary permit changes, the permitting authority may process a permit modification according to the requisite permit modification procedures (see Section III.B.2 of this preamble and proposed § 52.2454(n)). Any stakeholder may raise issues about the project at any time for discussion by the stakeholder group. The draft permit (Condition 6.1) identifies numerous issues that may be considered by the project stakeholders during each five year review, including: (1) Significant changes in emissions calculation methods; (2) changes in the list of criteria pollutants or the NAAQS; (3) review of example ''good environmental engineering practice'' control technologies required for significant new installations or modifications; (4) adequacy of the monitoring, recordkeeping and reporting requirements; (5) review procedure for compliance with newly-applicable criteria pollutant regulations; (6) review of the permit termination criteria; (7) review of ambient modeling for short-term PM_{10} and SO_2 emissions; (8) review of the determination that the area is NOx-limited for ozone formation; and (9) review of the periodic review criteria. In addition to these five-year review criteria, the stakeholders, including the National Park Service, also will be involved in considering project changes based on the review of the effects of VOC emissions on AQRVs in Shenandoah National Park and the review of the public health effects of VOC emissions, if VOC emissions at the site reach specified threshold levels. See Condition 6.2 of the draft PSD permit. The review criteria related to VOC emissions are described in more detail in Section III.B.1 of the preamble.

The draft PSD permit (Condition 12.6) defines ''project stakeholders'' as the project signatories to the FPA (i.e., EPA, VADEQ, Merck, DOI Federal Land Manager, and Rockingham County Board of Supervisors), plus other parties as follows: (1) Up to three other community representatives shall be included as nominated by the Rockingham County Board of Supervisors, and agreed to by full consent of the project signatories to the FPA. Community representatives are defined as local government and/or community residents with an ongoing stake in the project; and (2) Up to one representative from a regional public interest group shall be included as nominated by any project signatory and agreed to by full consent of the project signatories. This group of stakeholders will convene every five years to review whether changes to the permit are required. As discussed above, the draft permit establishes that full consent from the project signatories, and not each member of the stakeholder group, is necessary before permit changes can be made. This stakeholder process for five-year reviews is consistent with the process used in the development of the proposed FPA and draft permit. The Chairman of the Rockingham County Board of Supervisors is the signatory to the FPA (i.e., a project signatory) representing community interests. The three additional members of the community team (two neighbors of the Merck Stonewall Plant and the Town Manger of Elkton) also actively participated in the stakeholder group. The County was designated as a project signatory at the request of the community team in order to insure long-term representation and continuity of community interests.[3] This model of stakeholder involvement provided all stakeholders with full information and ability to shape the development of the project. EPA believes that it is an appropriate model which should apply in the same manner for the future evaluation of the project.

EPA has received comments expressing concerns about the adequacy of the role of the stakeholders who are not also signatories—the regional public interest group and the three community representatives other than the Rockingham County Board of Supervisors.[4] As described above, the draft permit establishes that full consent from the project signatories is needed to make permit changes (i.e., to recommend that the permitting authority process a permit modification). EPA interprets the permit to be designed such that the non-signatory stakeholders will be fully involved in the deliberation of all permit issues, as in the development of the Merck XL project. During the development of the Merck XL project, all stakeholders, as well as several environmental groups that were not part of the stakeholder group, provided valuable comments on the draft permit. These comments were fully considered by the project signatories and helped to shape the project. EPA expects that the same interaction among stakeholders will occur during the five-year permit reviews, and that the project signatories will fully consider concerns and issues raised by all the stakeholders before reaching decisions on permit changes. EPA invites public comment on the approach to stakeholder involvement

[3] See July 1, 1996 letter from the Merck XL community representatives to the County Administrator and Members of the Rockingham County Board of Supervisors (contained in the docket).

[4] See December 18, 1996 letter from David W. Carr, Jr., Staff Attorney, Southern Environmental Law Center, to EPA Administrator Carol Browner and Deputy Assistant Administrator Richard D. Wilson; December 18, 1996 letter from Betty S. Sellers, Community Representative-Merck XL Project, to EPA Administrator Carol Browner and Regional Administrator Michael McCabe; and December 20, 1996 letter from Betty S. Sellers to EPA Administrator Carol Browner and Deputy Assistant Administrator Richard D. Wilson (contained in the docket).

during the implementation of this XL project.

This XL project also greatly improves the stakeholders' access to information about the site's environmental performance. Merck will provide the stakeholders, and other interested parties, an annual progress report that describes the site's environmental performance under the XL project. This report will include a summary of the site's actual emissions and the total emissions cap and subcaps, a description of emissions prevented as a result of operating under this proposed rule and the PSD permit, and other information about the site's operations.

5. Compliance

Under the terms of this proposed rule and the draft PSD permit, Merck's actual emissions of criteria pollutants cannot exceed the total emissions cap, and emissions of SO_2, NOx and PM_{10} cannot exceed the individual subcaps for the life of the permit. Compliance with the site-wide total emissions cap and the subcaps will be determined by using a 12-month rolling total calculation of the site's actual emissions. The site-wide emissions will be calculated by using methods described in the permit. In addition to submitting to the project signatories semi-annual reports documenting the site's emissions, Merck will submit an annual progress report to the project stakeholders and other interested parties (as described in the previous section).

This proposed rule and draft permit will provide EPA and VADEQ with greater authority to enforce the terms of the permit. As with all permits, the permit terms can be enforced through standard procedures under the Clean Air Act (Act). In addition, unlike typical PSD permits, the draft permit expressly allows for termination of the permit under the following conditions: (1) If EPA or VADEQ determines that continuation of this permit is an imminent and substantial endangerment to public health or welfare, or the environment; (2) if Merck knowingly falsifies emissions data; (3) if Merck fails to implement the powerhouse conversion project within 30 months after the effective date of the PSD permit; (4) if Merck receives four consent orders or two judgments adverse to Merck arising from non-compliance with this permit in a five year period that are deemed material; (5) upon full consent of all project signatories; (6) if Merck's actual emissions exceed the total emissions cap; and (7) for other reasons for which the VADEQ has statutory authority to terminate the permit.

EPA and VADEQ will continue to possess all the administrative and judicial authority to enforce the provisions of the site-specific rule and permit that is currently available under sections 113 and 307 of the Act and under Virginia law.[5] This site-specific rule and the PSD permit would not limit the authority of EPA or VADEQ to take administrative enforcement measures or to seek legal or equitable relief to enforce the terms of this rule or the permit, including, but not limited to, the right to seek injunctive relief, and imposition of statutory penalties, fines and/or punitive damages. Further, this site-specific rule and the permit would not limit the authority of EPA or VADEQ to undertake any actions in response to conditions which present an imminent and substantial endangerment to public health or welfare, or the environment.

III. Clean Air Act Requirements

A. Summary of Regulatory Requirements for the Merck XL Project

The alternate regulatory system that would be established under this proposed site-specific rule and the draft permit addresses the existing criteria pollutants (and does not include lead). Merck will fully comply with all requirements for the control of HAPs, including the forthcoming Maximum Achievable Control Technology (MACT) standard for the pharmaceutical industry. Merck also will comply with all existing and future environmental requirements not specifically amended pursuant to EPA's site-specific rulemaking for this project or pursuant to the variance expected to be approved by the Commonwealth of Virginia.

In today's action, EPA proposes a site-specific PSD rule for the Merck Stonewall Plant in order to implement the proposed XL project for the site. See proposed § 52.2454. This site-specific rule would replace (in most circumstances) the existing PSD rules at 40 CFR 52.21 for the Merck Stonewall Plant only, and would establish the legal authority to issue the PSD permit to the Merck Stonewall Plant. The proposed site-specific PSD requirements are described in Section III.B.1 of this preamble.

EPA also proposes a site-specific rule which establishes an alternative means of compliance for the Merck Stonewall Plant for two New Source Performance Standards (NSPS)—Subpart Db (Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units) and Subpart Kb (Standards of Performance for Volatile Organic Liquid Storage Vessels). For NSPS other than Subpart Kb that may become applicable to the site in the future, EPA proposes an alternative compliance provision that would allow the facility the option of complying with the NSPS by reducing its site-wide emissions caps. However, under this latter approach, EPA has an opportunity to require Merck to comply directly with the applicable NSPS. These alternate compliance provisions are necessary to implement a simpler compliance approach for the facility that is more consistent with the principles of the site-wide emissions caps. The alternate compliance provisions are described further in Section III.D of this preamble.

On January 28, 1997, VADEQ initiated public comment on a proposed variance for the Merck Stonewall Plant, pursuant to section 10.1–1307 of the Virginia Air Pollution Control Law.[6] The VADEQ plans to request that the State Air Pollution Control Board approve the variance for Merck in April 1997. Among other things, the variance would provide Merck an alternate means of compliance with newly-applicable criteria pollutant regulations promulgated by the VADEQ. This alternate compliance option would allow Merck in most situations either to comply with new criteria pollutant regulations as written, or to reduce the total emissions cap (or subcaps, depending on the pollutant) by an equivalent amount of emission reductions. VADEQ also plans in the future to promulgate a source-specific regulation for the Merck XL project that would serve as an alternate to the regulations cited in the draft permit. EPA understands that VADEQ plans to submit this regulation to the EPA for approval as a source-specific SIP revision. EPA would then take action on the expected source-specific SIP revision in a future rulemaking action. This approach is described further in Section III.C of this preamble.

In addition to Clean Air Act requirements, the Merck XL project would establish alternate regulatory requirements for the Resource Conservation and Recovery Act (RCRA) air emission standards. These requirements are described in Section IV of the preamble.

[5] EPA plans to delegate the site-specific PSD rule (40 CFR 52.2454) to the VADEQ upon promulgation.

[6] This variance provision previously has been approved into the Virginia SIP at 40 CFR 52.2420(c)(15) and (89).

B. Prevention of Significant Deterioration

1. Requirements of the Clean Air Act

The NSR program is a preconstruction review and permitting program applicable to new or modified stationary sources of air pollutants regulated under the Act. In attainment areas (i.e., areas meeting the NAAQS), the NSR requirements for the prevention of significant deterioration of air quality (PSD) under part C of title I of the Act apply. The PSD provisions of the Act are a combination of air quality planning and air pollution control technology program requirements for new or modified stationary sources of air pollution. Each SIP is required to contain a preconstruction review program for the construction and modification of any stationary source of air pollution to assure that the NAAQS are achieved and maintained; to protect areas of clean air; to protect AQRVs (including visibility) in national parks and other natural areas of concern; to assure appropriate emission controls are applied; to maximize opportunities for economic development consistent with the preservation of clean air resources; and to ensure that any decision to increase air pollution is made only after full public consideration of all the consequences of such a decision. See sections 101(b)(1), 110(a)(2)(C) and 160 of the Act.

The Merck Stonewall Plant is located in an area that meets the NAAQS for all criteria air pollutants (attainment area) and, thus, the PSD program under part C of title I of the Act applies. Today, EPA proposes a site-specific PSD rule for the Merck Stonewall Plant in order to implement the proposed XL project for the site. Below, EPA describes how the proposed site-specific rule satisfies the statutory PSD permitting criteria in section 165(a) of the Act.

Sections 165(a)(1) and 169(2)(c) require Merck to obtain a permit for a proposed modification setting forth emission limitations which conform to the requirements of part C of title I of the Act. The proposed site-specific rule would authorize a permit to be issued to Merck based, in part, on the establishment of a site-wide emissions cap for criteria air pollutants (total emissions cap). The criteria pollutants included in the total emissions cap are SO_2, NO_X, PM_{10}, CO and ozone (using VOC as a surrogate). Thus, all existing criteria pollutants except lead are included in the total emissions cap. Merck would comply directly with any applicable requirements, including the existing PSD regulations at 40 CFR 52.21, for the control of lead emissions and any new criteria pollutants promulgated by EPA.[7] Further, Merck will comply with any applicable requirements, including the existing PSD regulations at 40 CFR 52.21 for emissions of non-criteria air pollutants (e.g., hydrogen sulfide, total reduced sulfur).[8]

This proposed rule would require the PSD permit to contain initial site-wide emissions caps based on the site's actual emissions during a time period, within five years of permit issuance, which represents normal site operation, or a different time period if it is more representative of normal source operation. The PSD permit that would be issued in accordance with the proposed site-specific rule would require the baseline for establishing the site-wide emissions caps to be the annual average of the facility's actual criteria pollutant emissions during 1992 and 1993, the recent years considered most representative of typical operations. Under the total emissions cap, emissions of SO_2, NOx and PM_{10} would also be capped (subcaps) at the 1992–93 actual emissions baseline. After the facility converts its coal-burning powerhouse to natural gas, the total emissions cap would be reduced by 20% from the baseline level. This cap adjustment will result in a permanent retiring of approximately 300 tons per year (TPY) of total criteria pollutants. Similarly, the subcaps for SO_2 and NOx will be reduced by 25% and 10%, respectively, after the powerhouse conversion. Detailed information about the establishment of the emission caps, including documentation of the baseline emissions calculations, is contained in the docket for today's action.

Merck will be allowed to vary its emission levels under the total emissions cap, constrained by the individual pollutant subcaps. Modifications at the facility that normally would be considered to result in emission increases would no longer need prior approval by the permitting authority under PSD or minor NSR, based on the facility's site-wide, federally-enforceable emission limitations. The emission limitations would keep SO_2 and NOx emissions well below recent actual emissions. The emission limitations for PM_{10} will not significantly increase above the recent actual emissions level. Emissions of VOC and CO will not have subcaps, however, the statutory PSD requirements for increases of VOC and CO will be satisfied pursuant to this site-specific rulemaking.

The individual pollutant subcaps for SO_2, NOx, and PM_{10} function similarly to plantwide applicability limits (PALs),[9] but with important distinctions. A PAL is an emissions cap established for a particular pollutant for PSD (or nonattainment NSR) applicability purposes only. Under a PAL, a source could make modifications without triggering PSD as long as emissions remain below the PAL. If a source needed to make a modification that would increase emissions above the PAL, the source would be able to make the modification after undergoing PSD or NSR review and obtaining the necessary permits. Unlike a PAL, under the site-specific rule and permit Merck will no longer be able to obtain additional PSD permits to increase emissions above the caps. In fact, pursuant to this site-specific rule, if Merck's emissions were to exceed the site-wide total emissions cap, the EPA or VADEQ could terminate the permit (See section II.B.5 of this preamble).

Section 165(a)(2) of the Act requires the proposed permit to be subject to a review in accordance with section 165 of the Act, the required analysis to be conducted in accordance with regulations promulgated by the Administrator, and a public hearing to be held. This proposed site-specific rule would establish the applicable site-specific PSD regulations for the Merck Stonewall Plant, and would therefore form the basis for the analysis required by section 165(a)(2) of the Act. The draft PSD permit that would be issued to the Merck Stonewall Plant under the authority of the new site-specific PSD rule is available to the public and contained in the docket file for this rulemaking. While the Agency may receive public comments on the draft PSD permit during the public comment period for this proposed rulemaking, in many instances the Agency may simply forward any such comments to VADEQ which will conduct the official public comment period and public hearing for

[7] The Commonwealth of Virginia currently implements 40 CFR 52.21 under a delegation of authority from EPA. See 40 CFR 52.2451.

[8] If Merck were to emit significant quantities of non-criteria air pollutants regulated under 40 CFR 52.21, Merck would be required to comply directly with any applicable requirements for these pollutants. For the Merck Stonewall Plant only, EPA proposes in this rulemaking to extend the policy set forth in the October 16, 1995 policy memorandum entitled ''Definition of Regulated Pollutant for Particulate Matter for Purposes of Title V,'' which is contained in the docket for this rulemaking, to consider PM_{10}, and not particulate matter, as the regulated form of particulate matter for purposes of PSD applicability.

[9] See New Source Review Reform proposal, 61 FR 38264–38266 (July 23, 1996).

the proposed permit.[10] On January 28, 1997, the VADEQ began a public comment period for the proposed PSD permit and a proposed variance that will serve as the Commonwealth's legal mechanism to issue the PSD permit to Merck. The VADEQ plans to request that the Virginia State Air Pollution Control Board approve the variance in April 1997. Once EPA's final site-specific rule for the Merck Stonewall Plant is promulgated, EPA plans to delegate to VADEQ the authority to issue the permit pursuant to the site-specific PSD rule. The VADEQ will have authority to issue the PSD permit to Merck after the Virginia State Air Pollution Control Board approves the variance and after this delegation is complete.

Section 165(a)(3) of the Act requires the owner or operator of a proposed major emitting facility to demonstrate that emissions from construction or operation of the facility will not cause or contribute to air pollution in excess of any (a) maximum allowable increase (PSD increments), (b) national ambient air quality standards (NAAQS), or (c) any other applicable emission standard or standard of performance.

Under the existing PSD rules at 40 CFR 52.21 (k) and (m), the Merck permit would not need a PSD increment or NAAQS compliance analysis, since emissions of SO_2 and NO_X will not be increased above baseline levels, and emissions of PM_{10} will not be increased significantly above baseline levels. Further, the subcaps for SO_2 and NO_X will be reduced by 25% and 10%, respectively, below baseline levels after completion of the powerhouse conversion. EPA proposes that this site-specific rule also not require a PSD increment or NAAQS compliance analysis for pollutants which will be capped near or below baseline emissions levels.[11] The draft PSD permit would not cause or contribute to emissions in excess of any other applicable emission standard or standard of performance. For more information, see the permit support document contained in the docket file and Sections III. C and D of this preamble.

To assure continued compliance with the NAAQS consistent with the minor NSR program, Merck conducted dispersion modeling to demonstrate that it does not cause or contribute to a violation of the short-term PM_{10} and SO_2 NAAQS. This modeling was based on worst case emission rates. The modeling results added to background levels indicate that the short-term NAAQS for PM_{10} and SO_2 would not be violated. Merck's maximum modeled impact was 15% of the 3-hour SO_2 NAAQS, 13% of the 24-hour SO_2 NAAQS, and 10% of the 24-hour PM_{10} NAAQS. Merck also modeled the worst-case CO emissions that could be achieved under the total emissions cap. The modeling demonstrated that Merck's maximum modeled impact would not exceed 1% of the CO NAAQS. The permit support document contained in the docket includes a description of the modeling analysis.

Based on the modeling results and other information provided in support of the draft permit, EPA believes that modifications at the site occurring within the first five year period of the permit that comply with this proposed rule and the permit will not cause or contribute to a violation of the NAAQS for the criteria pollutants included in the total emissions cap. Merck's ambient impact will be reevaluated as prescribed in the permit during each five year periodic review. Condition 6.1.7 of the draft permit requires that Merck perform an updated modeling analysis for SO_2 and PM_{10} at each five year review period, if requested by EPA or VADEQ, if major changes have been made at the site that are not reflected in the most recent modeling analysis. Merck must submit to the project stakeholders information necessary to determine whether additional modeling is required. Such information includes, but is not limited to, the following: (1) The current plant configuration, including building locations and dimensions; and (2) information on emission sources, including stack dimensions, operating parameters, and emission rates for actual operating conditions as well as worst case short-term (3 and 24-hour) operating conditions.

As Merck operates under the total emissions cap, it is permissible that over time VOC emissions will increase above the baseline VOC levels. The Merck Stonewall Plant is located in an area that is generally recognized to be NO_X-limited for ozone formation. The term ''NO_X-limited'' means that the amount of NO_X available is generally the controlling factor in determining how much ozone will be formed. In a NO_X-limited area, reduced NOx emissions will result in reduced ozone formation, and increased NO_X emissions will result in increased ozone formation. Further, increased VOC emissions generally will not result in additional ozone formation unless accompanied by additional NO_X emissions.

A report contained in the docket analyzed the worst case potential impact of VOC emissions on ozone formation in the area, based on an evaluation of urban airshed modeling developed for State Implementation Planning purposes in two urban areas. The potential for ozone formation was evaluated under the following worst case conditions: (1) If Merck were located in a VOC-limited area; (2) if the reactivity of Merck's VOC emissions were significantly higher than typical VOCs currently emitted at the facility (i.e., if the reactivity of Merck's VOC emissions were that of typical urban air or auto exhaust); and (3) if Merck's VOC emissions consumed the entire site-wide cap (i.e., a VOC emissions increase of approximately 600 TPY). Under this worst case scenario, which is highly improbable, the expected ozone increase from Merck's VOC emissions would be less than 1 $\mu g/m^3$ (.5 ppb), which is less than 0.5% of the ozone NAAQS. EPA believes that this is a highly conservative worst case analysis and that the potential ozone formation would be negligible under actual conditions. The worst case scenario is highly conservative because in actuality: (1) Merck is located in a NO_X-limited area; (2) the reactivity of the typical VOC emissions currently emitted by Merck is much lower than that of typical urban air or auto exhaust; and (3) it is unlikely that VOC emissions could consume Merck's entire site-wide cap, since a portion of the cap necessarily will be consumed by SO_2, NO_X, PM_{10} and CO from combustion sources (e.g., the natural gas-fired boilers) and other sources at the facility. Moreover, the NO_X emission reductions achieved as a result of Merck's powerhouse conversion and the establishment of permanent NO_X subcaps should help to reduce local ozone formation. Therefore, EPA believes that the maximum potential VOC emission increases allowed under Merck's site-wide cap will continue to provide protection of the ozone NAAQS.

One of the five-year periodic review criteria in the draft permit provides that any project stakeholder may present technical papers or studies that change the recognized determination that the area is NO_X-limited for ozone formation. Based on the stakeholders'' evaluation of this information, changes to the project may be considered if necessary.

Section 165(a)(4) of the Act requires the proposed facility to be subject to the best available control technology for each pollutant subject to regulation

[10] The VADEQ currently implements the PSD program at 40 CFR 52.21 under a delegation of authority from EPA. See 40 CFR 52.2451.

[11] Although VOC and CO emissions may increase, there are no PSD increments for VOC and CO.

under the Act emitted from such facility. Section 169(3) of the Act defines ''best available control technology'' (BACT) as an emission limitation based on the maximum degree of reduction of each pollutant subject to regulation under the Act emitted from or which results from any major emitting facility, which the permitting authority, on a case-by-case basis, taking into account energy, environmental, and economic impacts and other costs, determines is achievable for such facility through application of production processes and available methods, systems, and techniques, including fuel cleaning, clean fuels, or treatment or innovative fuel combustion techniques for control of each such pollutant.

Under the existing PSD rules at 40 CFR 52.21(j), the Merck permit would be required to apply BACT only for pollutants which would be allowed to increase above the significance levels in 40 CFR 52.21(b)(23). Under the site-wide emissions caps, VOC and CO are the only pollutants that can be increased above the existing PSD significance levels (i.e., 40 TPY for VOC and 100 TPY for CO). EPA proposes that this site-specific rule also require BACT (according to the interpretation proposed below) only for pollutants which will be allowed to increase significantly under the permit (i.e., VOC and CO). For purposes of this site-specific rule only, EPA proposes to interpret section 165(a)(4) to allow the BACT determination for the Merck Stonewall Plant to take into account the environmental impacts and benefits of foregoing traditional BACT for VOC and CO emission increases, and associated compliance costs, in favor of an innovative BACT determination for VOC and CO emission increases which relies on otherwise voluntary SO_2 and NO_X reductions from the powerhouse conversion and the site-wide emissions caps. Merck will implement the powerhouse conversion solely as a means of achieving superior environmental benefit under Project XL. There are no current or reasonably anticipated regulatory requirements that would require Merck to replace the coal boilers with natural gas boilers, and the boilers do not need to be replaced for other reasons (e.g., age, capacity, performance). The existing coal-fired boilers that will be replaced were installed in 1982 and have a useful life of about 40 years. Merck estimates that the powerhouse conversion will cost approximately $10 million in capital cost, and an additional $1 million per year in increased operational costs due to the currently higher price of natural gas.

The environmental benefits from the powerhouse conversion include over 900 TPY (60% of baseline) of up-front criteria pollutant emission reductions (SO_2 and NO_X) and about 47 TPY (65% of baseline) of HAP emissions reductions (hydrogen chloride and hydrogen fluoride). The 20 percent reduction of the total emissions cap after the powerhouse conversion will ''lock-in'' at least 300 TPY of these SO_2 and NO_X reductions. Further, Merck will have permanent site-wide emissions caps for SO_2 and NO_X, established at levels 25% and 10%, respectively, below recent actual emissions. These caps will permanently lock in a significant portion of the environmental benefit from the powerhouse conversion, and provide incentives for Merck to minimize actual emissions in order to preserve an operating margin for future growth. The environmental benefits from the powerhouse conversion and emissions caps include the following: (1) Visibility in nearby Shenandoah National Park should be improved from the SO_2 reductions; (2) acid deposition should be reduced from the substantial SO_2 and NO_X reductions, as well as the hydrogen chloride and hydrogen fluoride reductions; and (3) local ozone formation should be reduced from the NO_X reductions.

EPA proposes that the significant environmental benefits from the powerhouse conversion and site-wide emissions caps should be considered when determining appropriate BACT for future VOC and CO emission increases under the total emissions cap. EPA believes this is an approach that, while not the one historically adopted by the Agency under section 165(a)(4), merits consideration on a pilot project basis. If the project demonstrates that such an approach leads to superior environmental and economic results and if EPA determines that such an approach is transferrable to other situations, it could be considered for broader application. EPA emphasizes that this innovative approach to BACT determinations is not being adapted at this time for any source other than the Merck Stonewall Plant, and that the decision to make it available at this facility takes into account the totality of the obligations undertaken by Merck in this project. Thus, EPA believes that the BACT determination may consider the innovative nature of the site-wide emissions caps, and the tiered monitoring approach, in providing incentives for Merck to minimize actual emissions. In addition, the proposed rule would require Merck to install ''good environmental engineering practice'' technology on significant new installations or significant modifications for pollutants covered by the site-wide emissions cap. The draft PSD permit includes examples of emission controls that qualify as good environmental engineering practice technology in the pharmaceutical or batch processing industry. For example, for VOC control, the draft permit lists carbon adsorption, condensation, or thermal oxidation as example control technologies that could be used depending on the concentration and flow rate of the VOC streams. The EPA believes that the combination of substantial SO_2 and NO_X reductions, site-wide emissions caps, and the good environmental engineering practice requirement satisfy the statutory BACT requirement for possible VOC and CO emission increases as authorized in this site-specific rule.

There are several other aspects of the Merck XL project that will serve to keep VOC emissions well-controlled as Merck operates under the site-wide cap. First, Merck will comply with all requirements for the control of HAPs under section 112 of the Act, including the forthcoming MACT standard for the pharmaceutical industry. EPA expects that the pharmaceutical MACT standard will require control of emissions from process vents, wastewater, equipment leaks, and storage tanks. Merck's compliance with the pharmaceutical MACT will also provide co-control of some VOC emissions. For example, if a process vent stream contains HAPs as well as VOCs (or HAPs that are also VOC), the VOCs emissions would likely be controlled in accordance with the MACT standard. Second, Merck will conduct property line modeling of non-HAP VOCs to determine whether the emission levels are protective of public health. This modeling will be conducted when VOC emissions reach 125% of the VOC baseline (i.e., 510 TPY) and whenever VOC emissions increase by additional 100 TPY increments (i.e., 610 TPY, 710 TPY, and 810 TPY). This draft PSD permit provision (Condition 6.2.2) was developed to address the community stakeholders' concerns about the potential public health effects of Merck's VOC emissions. Third, the tiered monitoring provisions were designed to create an added incentive for Merck to minimize actual emissions. The monitoring, recordkeeping and reporting requirements increase in stringency as Merck's actual emissions approach the cap. This approach creates an incentive for Merck to minimize VOC emission increases, through the use of

good emissions control technology, pollution prevention, or other techniques, so that site-wide emissions remain in the lowest tier of monitoring.

The EPA acknowledges that the BACT provisions, as well as other provisions, of this proposed rule and the draft permit are in some ways in conflict with existing Agency guidance and interpretations of the Act. The Agency believes that it nonetheless has authority to apply today's proposed rule and the draft permit to Merck under Project XL as a unique, site-specific pilot project to explore and evaluate this innovative approach to environmental regulation consistent with the Act.

Section 165(a)(5) of the Act requires that major emitting facilities comply with the provisions of section 165(d) with respect to Federal Class I areas. Section 165(d)(2) provides that the FLM and the Federal official charged with direct responsibility for management of any Federal lands within a Class I area have an affirmative responsibility to protect the AQRVs (including visibility) of such lands. The FLM has a responsibility to consider, in consultation with the EPA Administrator, whether a proposed major emitting facility will have an adverse impact on any AQRV.

The U.S. Department of the Interior (DOI) is the FLM for the Shenandoah National Park, a Federal Class I area within 2 kilometers of the Merck Stonewall Plant. The DOI, specifically the National Park Service (NPS), is a key stakeholder in developing the Merck XL project. Issues involving the potential impacts of the project on AQRVs in the Park were discussed at length among the project stakeholders. Because Merck will convert its powerhouse from burning coal to natural gas, the proposed XL project will achieve significant up-front reductions of SO_2 and NO_X, two pollutants associated with existing adverse impacts on the Park.[12] Another pollutant of concern is ozone, because of its potential effects on park resources, such as vegetation. However, ozone levels are not expected to increase as a result of this project. As explained above, the area generally is considered to be NO_X-limited for purposes of ozone formation and, therefore, increases in VOC emissions are not expected to cause increased ozone levels without additional increases of NO_X. Thus, the allowable increase of VOC emissions under Merck's total emissions cap is not likely to contribute significantly to ozone formation, as described above. Moreover, the Merck XL project should help reduce the formation of local ozone due to decreases in NO_X emissions.

Aside from the impact of VOC emissions as a precursor to ozone formation, the FLM also expressed concern during the Merck XL stakeholder discussions regarding the potential impacts of future VOC emissions increases directly on AQRVs in the Park. Therefore, the draft PSD permit for the Merck XL project requires Merck to evaluate the effects of VOC on AQRVs in the Park upon certain ''trigger levels'' of VOC emission increases. Merck will perform an AQRV assessment upon either of the following events: (1) After the first time the site-wide VOC emissions reach a level that is double the baseline VOC emissions (i.e., if site-wide VOC emissions reach 816 TPY); or (2) after installation of any individual new process or process modification that results in a net emissions increase of the site's actual VOC emissions of 100 TPY or more. Under condition 6.2.1 of the draft permit, if the project signatories agree that Merck's VOC emissions are the cause of adverse impact on any AQRVs at the Federal Class I area, Merck shall implement mitigation measures that are agreed to by the project signatories. However, Merck does not have the obligation under the permit to mitigate if there are other contributing sources to the AQRV adverse impact.

EPA believes that it has the authority under the Clean Air Act to address adverse impacts on AQRVs in Federal Class I areas from both new and existing sources. EPA intends to undertake a future rulemaking to require State Implementation Plans to prevent significant deterioration of air quality by adopting mitigation measures to address such adverse impacts. Merck agrees that EPA should undertake the rulemaking approach, described above, to address environmental problems indicated by adverse impacts on AQRV's in Federal Class I areas.

DOI also expressed an interest in further understanding the impacts of VOC emissions generally on resources in Shenandoah National Park. EPA and DOI have agreed to work cooperatively to better understand background VOC levels in the Park, through monitoring, sampling or other appropriate analyses, and their potential impacts on park resources.[13]

Section 165(a)(6) of the Act requires an analysis of any air quality impacts projected for the area as a result of growth associated with the proposed permit. The Merck Stonewall Plant is an existing source, in operation since 1941. There is not expected to be any significant growth associated with the Merck Stonewall Plant in the area that would affect air emissions.

Section 165(a)(7) of the Act requires the owner or operator to conduct monitoring as may be necessary to determine the effect which emissions increases may have, or are having, on air quality. Under the Merck XL project, Merck will not have a significant increase of SO_2, NO_X or PM_{10} above baseline levels. Moreover, allowable SO_2 and NO_X emissions (i.e., subcaps) will be reduced from the actual emissions baseline levels by 25% and 10%, respectively, after the powerhouse conversion. As described above, Merck has conducted modeling to demonstrate that its maximum possible CO emissions under the cap would consume less than 1% of the NAAQS. Because the area is NO_X limited for ozone formation and the Agency believes that the maximum potential VOC emission increases allowed under Merck's total emissions cap will not increase ozone levels (see previous discussion in this section of the preamble), EPA does not believe that Merck's allowable VOC emission increases warrant a requirement to conduct ambient ozone monitoring. Therefore, EPA believes that there are no ambient monitoring requirements necessary to satisfy this provision of the Act for the Merck project.

2. Permit Modifications

As described in Section II.B.4 of the preamble, the stakeholders will periodically review the PSD permit and consider whether any changes are required. Changes to the permit may be made either after full consent of the project signatories and subject to the permit modification procedures promulgated in this site-specific rule, or pursuant to PSD permit modification procedures generally applicable to other PSD permits.[14]

As part of the site-specific PSD rule, EPA is proposing procedures to be followed by the permitting authority for

[12] See 55 FR 38403–38408 (September 18, 1990).

[13] See October 16, 1996 letter from Richard D. Wilson, Deputy Assistant Administrator, Office of Air and Radiation, U.S. Environmental Protection Agency, to George Frampton, Assistant Secretary for Fish and Wildlife and Parks, U.S. Department of the Interior; and October 17, 1996 letter from George T. Frampton to Richard D. Wilson (contained in docket file).

[14] EPA has not promulgated general procedures to modify PSD permits. See 40 CFR 124.5(g)(1). The language in the draft PSD permit is intended to provide that if the Agency were to promulgate generally applicable regulations, not solely applicable to the Merck PSD permit, establishing the procedures for sources and permitting authorities to modify PSD permits, then the Merck PSD permit also would be subject to such procedures.

processing modifications to the Merck PSD permit. See proposed § 52.2454(n). These provisions also define criteria for the types of changes that may be processed as PSD administrative permit modifications. See proposed § 52.2454(n)(2). These procedures apply only to the permit issued pursuant to the site-specific PSD rule for the Merck Stonewall Plant.

C. State Implementation Plan Requirements

The Merck XL project would involve alternative compliance provisions for several Virginia SIP requirements. In the next few months, prior to issuance of the Merck PSD permit, VADEQ plans to propose that the Virginia State Air Pollution Control Board approve a variance for the Merck Stonewall Plant, pursuant to section 10.1–1307 of the Virginia Air Pollution Control Law. This variance provision previously has been approved into the Virginia SIP at 40 CFR 52.2420(c) (15) and (89). The variance would allow Merck to operate under the PSD permit, which represents compliance for the Virginia regulations cited in Section 3 of the draft permit. The permit support document contained in the docket file for this rulemaking describes the basis for determining that the XL project should serve as alternative compliance to these regulations. VADEQ also plans in the future to promulgate a source-specific regulation for the Merck XL project that would serve as an alternate to the regulations cited in the draft permit. VADEQ plans to submit this regulation to the EPA for approval as a source-specific SIP revision. EPA would then take action on the expected source-specific SIP revision in a future rulemaking action.

One of the key SIP requirements that the Merck XL project will replace is minor NSR permitting. The new PSD permit would replace the previously-issued minor NSR permits for the Stonewall Plant. Merck currently has 14 minor NSR permits for the Stonewall Plant. Pursuant to the variance and SIP revision procedure described above, this proposed rule and the draft permit would be substituted for the existing Virginia minor NSR SIP program for the Merck Stonewall Plant. The draft PSD permit requires Merck to continue to operate and maintain the emission control equipment that is currently permitted. By operating under the permit, including the site-wide emissions caps, modifications at the facility would not be required to undergo traditional minor NSR permit reviews.

If the area in which the Merck Stonewall Plant is located becomes a nonattainment area for any of the criteria air pollutants included in the total emissions cap, the facility will be grandfathered from any new nonattainment NSR requirements, as long as the PSD permit issued pursuant to this proposed site-specific rulemaking is in effect. This is because the PSD permit authorizes construction and operation of any new or modified sources of emissions of the pollutants included in the total emissions cap. All changes at the facility covered by the PSD permit would not be subject to any additional major NSR permitting requirements, whether PSD or nonattainment NSR. This grandfathered status does not apply to any other Title I nonattainment requirements (see the following discussion pertaining to newly applicable criteria pollutant regulations).

The draft permit also contains provisions for Merck to comply in an alternative means with applicable future criteria pollutant regulations [15] including regulations promulgated pursuant to the AQRV SIP rulemaking described above. Under this approach, Merck would have the option of either complying with a new criteria pollutant regulation as written, or by reducing its total emissions cap or subcaps (depending on the pollutant). If Merck chooses the option of reducing its total emissions cap or subcaps, Merck would determine the reduction in total actual emissions that would result from complying with the regulation, and reduce its total emissions cap or subcaps by that amount. If the criteria pollutant regulation would result in the control of SO_2, NO_X, or PM_{10}, Merck would reduce its subcaps for SO_2, NO_X, or PM_{10}, respectively (or comply directly with the applicable regulation). If the criteria pollutant regulation would result in the control of VOC or CO, Merck would reduce its total emissions cap (or comply directly with the applicable regulation). The draft permit sets forth the process by which the administering agency (EPA or VADEQ) will approve Merck's emission reduction determination. For certain types of criteria pollutant regulations, namely, Federal Implementation Plans (FIP) and most NSPS, EPA will determine whether such alternative compliance provisions are appropriate, as discussed below. For SIP requirements, this approach is contingent on authorizing language in the Virginia SIP, which will be accomplished initially through Virginia's approval of a variance. (See previous discussion in this section). The permit support document contained in the docket describes this approach in more detail.

This alternative compliance option is a significant element of the overall Merck XL project. Merck has expressed that this option could be useful when, for example, a rule requires controls on an emission unit(s) that Merck may be planning to shut down or replace soon after the rule's compliance date (e.g., phase-out of certain pharmaceutical products) and it would not be cost-effective to comply with the rule directly. As another example, Merck may decide that it should achieve actual emission reductions to keep site-wide actual emissions well below the cap (e.g., within Tier I monitoring), but the new rule will not result in cost-effective reductions. In this case, Merck could choose to reduce the cap in lieu of complying directly with the regulation, but may voluntarily install more effective emission controls on other emission units to minimize site-wide actual emissions and preserve its operating margin under the caps.

The Commonwealth of Virginia plans to include this compliance option for the Merck Stonewall Plant for SIP rules in a future source-specific SIP revision. EPA believes that it is acceptable to allow such a source-specific compliance option for SIP purposes as part of the Merck XL project, because it is the Commonwealth's responsibility to design SIP control strategies that ensure that the area attains and maintains the NAAQS, and the Commonwealth generally determines which sources must achieve emissions reductions. Virginia is making an up front decision that, for future SIP regulations, the Commonwealth may not achieve planned levels of actual emission reductions from the Merck Stonewall Plant as a result of such regulations (i.e., if Merck chooses to reduce its total emissions cap or subcaps instead). EPA has informed Virginia that the Commonwealth could not receive emission reduction credit in an attainment plan if Merck chooses the option of reducing its site-wide cap or subcaps. If the criteria pollutant regulation is promulgated by EPA in a FIP, it would be EPA's responsibility to ensure adequate emission reductions to attain and maintain the NAAQS. Therefore, if Merck is subject to a future FIP requirement for criteria pollutants covered by the total emissions cap the

[15] These provisions apply only to regulations that would apply to the criteria pollutants included within the site-wide emissions cap and listed in Section 1.1 of the draft permit, namely SO_2, NO_X, PM_{10}, CO, and ozone (using VOC as surrogate).

draft permit provides that EPA will determine whether it is appropriate for Merck to have the option of reducing the total emissions cap or subcaps in lieu of complying with the FIP regulation.

D. New Source Performance Standards

EPA is proposing a site-specific rule that would establish an alternate means of compliance for the Merck Stonewall Plant for two existing New Source Performance Standards (NSPS)—Subpart Db (Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units) and Subpart Kb (Standards of Performance for Volatile Organic Liquid Storage Vessels)—as well as for future applicable NSPS. These alternate compliance provisions are necessary to implement a simpler compliance approach for the facility that is more consistent with the principles of the site-wide emissions cap.

A key innovation in this XL project is to demonstrate that incentives to minimize emissions can be achieved through compliance with a site-wide total emissions cap, established at a level 20 percent below recent actual emissions (i.e., an ''actuals-based'' cap), as well as subcaps for SO_2, NO_X, and PM_{10}. Thus, under this project, total criteria pollutant emissions must decrease substantially from recent actual emissions. Under this proposed rule and the draft permit, Merck would achieve significant environmental benefits by converting its coal-burning powerhouse to natural gas and by complying with the actuals-based site-wide emissions caps.

Under the existing regulations, the new natural-gas fired boilers would be subject to NSPS Subpart Db. EPA proposes to promulgate a site-specific NSPS rule establishing an alternate means of compliance for the Merck Stonewall Plant's planned natural gas-fired boilers that would be subject to NSPS Subpart Db. See proposed § 60.49b(u). The key emission limitation requirement of NSPS Subpart Db for natural gas-fired boilers is a NO_X emissions standard of 0.10 lb/mmBTU heat input. The proposed alternate compliance provisions would require Merck to install low-NO_X technology on the new natural gas-fired boilers instead of meeting a specific NO_X emission standard for the boilers. See proposed § 60.49b(u)(1)(i). The requirement to comply with the total emissions cap (established at a level 20 percent below recent actual emissions), as well as the NO_X subcap, establishes an incentive to minimize actual emissions. In selecting low NO_X technology for installation with the new natural gas boilers, Merck plans to install technology that will achieve a NO_X emission rate of 0.035 lb/mmBtu—an emission rate well below the applicable NSPS standard. The docket file contains a letter from Merck stating its commitment to specify low NO_X technology that will achieve a NO_X emission rate of 0.035 lb/mmBtu or less when seeking bids for the new boilers.[16]

Under the alternate compliance provisions, Merck would be required to perform emissions testing and monitoring requirements that are substantively equivalent to the requirements of NSPS Subpart Db, including the emissions monitoring requirements in 40 CFR 60.48b. Merck would be required to perform a stack test within 180 days of completing the powerhouse conversion to quantify the criteria pollutant emissions from the new boilers. Merck also would be required to continuously monitor and record NO_X and opacity using a continuous emissions monitoring system or predictive emissions monitoring system.

EPA also proposes to promulgate a site-specific NSPS rule establishing an alternate means of compliance for volatile organic liquid (VOL) storage vessels (including petroleum liquid storage vessels) that would be subject to NSPS Subpart Kb. See proposed § 60.112b(c). The recordkeeping provisions of 40 CFR 60.116b (b) and (c) require certain records to be kept depending on the size of the vessel and the vapor pressure of the VOL stored. At this time, the Merck Stonewall Plant operates VOL storage vessels that are subject only to these recordkeeping requirements. EPA believes that the monitoring, recordkeeping and reporting requirements of this proposed rule and the draft PSD permit are adequate to ensure compliance with the provisions of the draft PSD permit at the site. Therefore, EPA proposes that, for storage vessels not subject to the control technology requirements of Subpart Kb (see discussion below), the requirements of 40 CFR 60.116b (b) and (c) and the NSPS General Provisions (40 CFR Part 60, Subpart A) not be applicable to the Merck Stonewall Plant. See proposed § 60.112b(c)(2).

For storage vessels with a certain design capacity and storing a VOL with a certain vapor pressure, Subpart Kb (40 CFR 60.112b (a) and (b)) requires that the storage vessels be equipped with control technology. The control technology options of 40 CFR 60.112b(a) include: (1) A fixed roof tank with an internal floating roof; (2) an external floating roof; (3) a closed vent system and control device with 95% control efficiency; and (4) a system of equivalent control to options 1–3. In addition, certain EPA notifications are applicable for such new or modified facilities in accordance with the NSPS General Provisions (Subpart A). Storage vessels storing material with high vapor pressures do not have the option to use floating roof controls, but must be equipped with a closed vent system and control device or meet an equivalent standard (40 CFR 60.112b(b)). Merck currently has no storage vessels that are subject to the Subpart Kb control technology requirements. EPA also proposes to promulgate a site-specific NSPS rule establishing an alternate means of compliance that would apply if in the future Merck installs such storage vessels, or changes the operation of existing storage vessels, such that they would otherwise be subject to the control technology requirements of Subpart Kb (40 CFR 60.112b (a) or (b)). EPA proposes that Merck would have the option of reducing the site-wide emissions cap in lieu of complying directly with the NSPS Subpart Kb requirements. This option would be implemented in the same manner as that described above for alternate compliance for SIP rules (see Section III.C of this preamble). See proposed § 60.112b(c)(1) and condition 1.2.2.c.iii. of the draft PSD permit.

For future applicable NSPS other than Subpart Kb, including future promulgated NSPS, this proposed rule and the draft permit would allow Merck to seek the same alternative compliance option as for Subpart Kb, that is, the option to reduce the site-wide emissions cap(s) in lieu of complying directly with the applicable NSPS rule. See proposed § 60.1(d). However, the proposed rule and draft permit provide EPA an opportunity to require Merck to comply with the NSPS regulation as written, rather than exercise the option to reduce the site-wide emissions cap(s). See proposed § 60.1(d)(3). Condition 1.2.2.c.iii. of the draft PSD permit provides that, for any NSPS other than Subpart Kb, Merck shall implement the regulation as written by the compliance date if: (1) EPA determines that compliance with the regulation instead of a cap adjustment is necessary for achieving the objectives of the regulation, and (2) EPA notifies Merck in writing within 60 days of Merck's notification that it is newly subject to the regulation.

[16] See letter dated December 11, 1996 from Mr. Tedd Jett, Manager of Environmental Engineering, Merck & Co., Inc., Stonewall Plant, included as Appendix 4 of the PSD permit support document (contained in the docket).

EPA emphasizes that the alternative approaches to compliance with Clean Air Act requirements adopted in this rule are being adopted only for this facility, on a pilot project basis. The approach is not available to other facilities, and the decision to make it available at this facility is linked to the full set of the facility's obligations in this project. Based on the experience in this project, EPA could propose to adopt such an approach more widely at some future time, but the rule proposed today is limited to the Merck Stonewall Plant and should not be interpreted as a more general revision of NSPS regulations, or even as initiating a process toward such a general revision.

E. Title V Operating Permit

Today's proposed site-specific rulemaking does not amend or add any new Title V requirements for the Merck Stonewall Plant. Merck will be required to obtain a Title V operating permit, pursuant to the applicable Title V program in the Commonwealth of Virginia. The 40 CFR Part 71 Federal Operating Permit Program is currently effective in Virginia.[17] However, EPA plans in the near future to propose approval of Virginia's Title V program pursuant to 40 CFR Part 70 (State Operating Permit Programs), which, when finalized, would replace the Part 71 program in Virginia. EPA expects that Merck's Title V permit would be issued under Virginia's Title V program after it is approved, rather than under the Part 71 program requirements. However, Merck has requested that EPA clarify some interpretations about how the Part 71 program would apply to the facility, particularly, how the provisions of the PSD permit would be treated as an underlying set of applicable requirements within the Title V permit.

As part of Merck's Title V permit, the new PSD permit would become the principal set of applicable requirements for criteria pollutants for the facility. Other applicable requirements would include the future pharmaceutical MACT and any other requirements pertaining to HAP emissions, any SIP or NSPS rules that the facility complies with directly, as well as any other rules promulgated in the future that would apply to the facility.

The draft PSD permit has substantial requirements for monitoring, recordkeeping and reporting in order to ensure compliance with the PSD permit. As described previously in this preamble, the monitoring, recordkeeping and reporting provisions of the PSD permit increase in stringency as Merck's emissions approach the total emissions cap. EPA does not believe that any additional monitoring requirements (e.g., periodic monitoring or ''gap-filling'') would need to be added to Merck's Title V permit in order to demonstrate compliance with the PSD permit. Therefore, EPA interprets that the monitoring, recordkeeping and reporting requirements of the PSD permit constitute compliance with the monitoring requirements of 40 CFR 71.6(a)(3) that would be applicable to the PSD permit (as a set of applicable requirements in the Title V permit). Similarly, EPA interprets that the recordkeeping and reporting requirements of the draft PSD permit satisfy compliance with the recordkeeping and reporting requirements of 40 CFR 71.6(a)(3)(ii) and 71.6(a)(3)(iii)(A) that would be applicable to provisions of the PSD permit (as a set of applicable requirements in the Title V permit). See condition 3.4.2 of the draft PSD permit. Further, EPA intends that the forthcoming Compliance Assurance Monitoring (CAM) rule would not impose additional monitoring requirements through Merck's Title V permit for applicable requirements in the PSD permit.

Merck also wants to ensure that the Title V permit modification provisions would not undermine the flexibility gained through the XL project. Because the draft PSD permit would not require modifications at the site to undergo case-by-case permitting approval, so long as Merck is in compliance with the site-wide emission caps, EPA expects that there would be relatively few changes at the site that would necessitate a Title V permit revision. Merck specifically asked EPA to clarify what type of Title V permit revision process would apply to an operational change that would add, delete or otherwise change Title V permit terms related to MACT standards promulgated under 112(d) of the Act (e.g., adding a process unit that would be subject to MACT permit terms already listed in the permit for other emission units). Under the existing 40 CFR 70 and 71, EPA interprets that the minor permit modification process generally would apply to a change at the site that would affect permit terms related to MACT standards, so long as the change did not specifically meet the conditions for a significant permit modification (e.g., relaxation of applicable monitoring, recordkeeping or reporting requirements). The minor permit modification would apply in a situation where a physical change or a change in method of operation of a source changed the applicability of a 112(d) standard by deleting an existing 112(d) requirement that no longer applied to the source. For example, if use of a storage tank is changed from storage of a high vapor pressure solvent to a low vapor pressure solvent, that change in method of operation may eliminate a 112(d) requirement to control emissions from the tank and perhaps add a new recordkeeping requirement. Such a change in the applicability of the 112(d) standard to the source would not be considered a ''relaxation of monitoring, recordkeeping and reporting requirements,'' and therefore, would qualify for the minor permit modification procedure. The minor permit modification process allows the source to operate the change immediately after the source files the Title V permit application for the modification. EPA plans to promulgate final revisions to the Part 70 regulations in the near future. EPA expects that the final Part 70 rules may provide options for an even more streamlined permit revisions process for certain types of changes to MACT permit terms.

IV. Resource Conservation and Recovery Act Requirements

The RCRA subpart AA, BB, and CC air emission standards under 40 CFR parts 264 and 265 are applicable to certain existing hazardous waste units at the Merck Stonewall Plant. These standards also may be applicable to equipment brought into hazardous waste service in the future. The RCRA air standards contain both substantive emission control requirements and administrative requirements (e.g., reporting and recordkeeping) applicable to certain hazardous waste management units. Under this XL project, the Merck Stonewall Plant will be subject to a site-specific exemption from the RCRA air emission standards under 40 CFR parts 264 and 265. Additionally, the Merck Stonewall Plant will be subject to an enforceable PSD permit, as described in Section II.B.2 of this preamble, and will continue to conduct a preventive maintenance program. Although the PSD permit and the preventive maintenance program address both inorganic and organic air emissions from many types of units located at the plant, the RCRA air emission standards only address organic air emissions from RCRA hazardous waste management units.

The following hazardous waste management equipment is currently in operation at the Merck Stonewall Plant: A RCRA-permitted container storage area; three accumulation tanks; less than

[17] See 61 FR 34202–34249 (July 1, 1996).

90-day accumulation containers; three pumps; approximately 50 valves; and associated fittings (e.g., flanges and sampling connections). In absence of this XL project, this hazardous waste management equipment would be subject to both the substantive and administrative requirements contained in the RCRA air standards. Any new hazardous waste management units, or existing units newly placed in hazardous waste service, would also be subject to those substantive and administrative requirements.

For hazardous waste tanks and containers located at the Merck Stonewall Plant, the PSD permit includes air emission control requirements that are identical to the substantive requirements under the RCRA air standards. For process vents that would otherwise be subject to the subpart AA process vent regulations, and for equipment that would otherwise be subject to the subpart BB equipment leak regulations, the Merck Stonewall Plant will implement air emission control requirements that are similar, though not identical, to those that are included in the nationwide standards.

For all affected hazardous waste equipment, this site-specific regulation will exempt the Merck Stonewall Plant from the administrative requirements of the RCRA air standards; the PSD permit and, when issued, the Clean Air Act (CAA) Title V permit, will subject the plant to alternative administrative requirements. The nationwide RCRA air standards contain an allowance that a unit operated with air emission controls, in compliance with a CAA standard in 40 CFR parts 60, 61, or 63, is exempt from the RCRA standards. Among other requirements, this nationwide allowance exempts a unit from the administrative requirements of the RCRA air standards, provided that the air emission controls on that unit are operated in compliance with the requirements of the CAA part 60, 61, or 63 standard, including administrative requirements. In such cases, the administrative requirements would ultimately be enforceable through a CAA permit. Under this XL project, the Agency is allowing the Merck Stonewall Plant to comply with the administrative requirements that will be contained in the plant's CAA PSD and Title V permits, which is analogous to the existing nationwide RCRA air standards provision that allows facilities the alternative to operate air emission controls in compliance with standards under 40 CFR parts 60, 61 or 63. Thus, the Agency considers the administrative requirements under this XL project for affected hazardous waste management units at the Merck Stonewall Plant to be equivalent to the administrative requirements of the nationwide RCRA air standards.

The Merck Stonewall Plant does not currently have any units or emission points that would be subject to the subpart AA process vent standards. Over the life of the PSD permit, it is conceivable that the Merck Stonewall Plant may make facility or process alterations resulting in emission points that become newly subject to subpart AA. To address this possibility, the terms of the PSD permit require the Merck Stonewall Plant to route any hazardous waste process vent emissions to a secondary brine condenser or thermal oxidizer, and monitor the performance of these organic control devices. The subpart AA nationwide standards would require that these process vent emissions be routed to a 95% organic emission control device and monitor control device performance, only if the total facility-wide hazardous waste process vent emissions exceed 3.1 tons per year or 3 pounds per hour. However, under the PSD permit, all hazardous waste process vents which would otherwise be subject to subpart AA will be controlled for organic emissions, regardless of the facility-wide emission rates. Because the PSD permit will require organic air emission controls on each hazardous waste process vent operated at the Merck Stonewall Plant, the Agency considers that compliance with the PSD permit will achieve greater emission reductions from these hazardous waste process vents than would be achieved by compliance with the nationwide subpart AA standards.

For subpart BB leak detection and repair requirements, the Merck Stonewall Plant does have hazardous waste management units that are subject to the RCRA air standards. Under this XL project, the Merck Stonewall Plant will be addressing the organic emissions which would otherwise be addressed through compliance with the subpart BB nationwide standards, through the continued performance of a preventive maintenance program that is in place at its facility. This maintenance program is applicable to all existing and future equipment that would otherwise be subject to the nationwide subpart BB standards. The program includes semi-annual, quarterly, and monthly visual inspections, depending on the equipment type, and routine maintenance and repair procedures. The Merck Stonewall Plant has submitted site-specific leak rate data for subpart BB equipment which has been subject to this program; that data indicates low leak rates and low incidence of leaking equipment for all the hazardous waste components at the plant. For this XL project, the Agency is assuming that the continued performance of this program will result in similar leak rates over the life of the PSD permit.

The sampling connection systems and open-ended valves or lines that would otherwise be subject to subpart BB standards are designed and operated in a manner consistent with the requirements of the subpart BB standards. The preventive maintenance program includes periodic visual inspections and subsequent repair of detected leaks for flanges and other connectors, which is consistent with the subpart BB requirements under 40 CFR part 264.1058(a) for that equipment. Because the Merck Stonewall Plant preventive maintenance program includes these requirements, the Agency is assuming that this program will effectively accomplish the same organic emission controls as the substantive subpart BB nationwide standards for flanges and other connectors, sampling connection systems, and open-ended valves or lines at that Plant.

The EPA has reviewed facility-specific component leak rate data provided by the Merck Stonewall Plant and found that less than 2% of the affected valves leak, and none of the three hazardous waste pumps leak or have detectable emissions. Under the provisions of subpart BB in 40 CFR part 264.1061, a facility at which less than 2% of affected valves leak can choose to comply with subpart BB through a performance standard that includes an annual performance test using EPA Method 21 instrument monitoring. Under subpart BB in 40 CFR part 264.1052, these hazardous waste pumps, which are in light liquid service, would be subject to monthly leak detection and repair monitoring using EPA Method 21. Under this XL project, this hazardous waste equipment will be exempt from the subpart BB standards. Instead, the Merck Stonewall Plant will include this hazardous waste equipment in their preventive maintenance program; this program includes visual inspection of all valves and pumps and repair of any detected leaks. In allowing this alternative for the Merck Stonewall Plant, the Agency is assuming that the preventive maintenance program for valves and pumps will maintain the low leak rates that have been previously demonstrated for these existing hazardous waste valves and pumps, and will achieve similarly low leak rates for any valves and pumps placed in hazardous waste service in the future. The component-

specific leak rates demonstrated for this equipment are within the range that the Agency would expect to be achieved by compliance with the subpart BB nationwide standards for hazardous waste valves and pumps. The preventive maintenance program has been in place at the Merck Stonewall Plant for several years, and the EPA is assuming that the very low leak rates for the affected equipment have resulted from a combination of: the effectiveness of the Merck Stonewall Plant preventive maintenance program; the quality of the valves, pumps and associated equipment that are used at the plant; the properties of the hazardous waste which this equipment contacts; and the specific parameters for the hazardous waste processes. The Agency is also assuming that requiring the Merck Stonewall Plant to continue this preventive maintenance program under this XL project will preserve the low component leak rates for hazardous waste management units at the plant.

For subpart CC standards applicable to tanks and containers, the Merck Stonewall Plant is currently in compliance with the substantive organic air emission control requirements of those nationwide standards. For the hazardous waste containers at the Merck Stonewall Plant, the nationwide subpart CC standards would require that the containers be operated with covers that have no visible openings; the PSD permit includes this same requirement for all hazardous waste containers currently operated, or operated in the future, at the plant. For the hazardous waste accumulation and/or storage tanks at the Merck Stonewall Plant, the nationwide subpart CC standards would require that the tanks be operated with a cover that has no visible openings or gaps; the PSD permit contains this same requirement for all hazardous waste accumulation and/or storage tanks currently operated, or operated in the future, at the plant. The Merck Stonewall Plant does not operate any hazardous waste tanks that would be classified as Level 2 tanks under the RCRA subpart CC standards. However, it is conceivable that during the life of the PSD permit, the plant may operate this type of tank. To address this possibility, the PSD permit contains a requirement that any hazardous waste treatment tank operated at the plant must be equipped with a fixed cover and either a floating roof or a vent system that routes the tank emissions to a secondary brine condenser or a thermal oxidizer. These requirements are among the compliance options allowed under the nationwide subpart CC standards, and would constitute compliance with the substantive requirements of those nationwide standards. Therefore, the Agency considers the requirements of the PSD permit for the hazardous waste containers and tanks at the Merck Stonewall Plant to be the same as the substantive requirements of the nationwide RCRA air rules for those units.

The Merck Stonewall Plant does not currently operate any hazardous waste surface impoundments, nor do they expect to operate any in the future. For this reason, the Plant is not seeking relief from the surface impoundment RCRA air emission standards. The Merck Stonewall Plant has agreed that any hazardous waste surface impoundment that may be operated at the facility in the future will be installed and operated to comply with the applicable requirements of the nationwide subpart CC air emission standards. Therefore, the site-specific regulation exempts the Merck Stonewall Plant from all the subpart CC requirements except for the requirements that are applicable to surface impoundments.

Overall, the Agency considers this to be a viable approach to addressing organic air emission from hazardous waste units, which is worthy of further evaluation through the Project XL program.

V. Additional Information

A. Public Hearing

A public hearing will be held, if requested, to provide opportunity for interested persons to make oral presentations regarding the proposed regulation in accordance with section 307(d)(5) of the Clean Air Act. Persons wishing to make oral presentation on the proposed rule to implement Merck's XL project should contact the EPA at the address given in the **ADDRESSES** section of this document. Any member of the public may file a written statement before, during, or within 30 days after the hearing. Written statements should be sent to EPA at the addresses given in the **ADDRESSES** section of this document. If a public hearing is held, a verbatim transcript of the hearing and written statements will be available for inspection and copying during normal business hours at the EPA addresses given in the **ADDRESSES** section of this document.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993) the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, of State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs of the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Because the annualized cost of this final rule would be significantly less than $100 million and would meet none of the other criteria specified in the Executive Order, it has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866, and is therefore not subject to OMB review.

C. Regulatory Flexibility

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule would not have a significant impact on a substantial number of small entities because it only affects one source, the Merck Stonewall Plant, which is not a small entity. Therefore, EPA certifies that this action will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

This action applies only to one company, and therefore requires no information collection activities subject to the Paperwork Reduction Act, and therefore no information collection request (ICR) will be submitted to the Office of Management and Budget (OMB) for review in compliance with the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

As noted above, this rule is limited to Merck's facility in Elkton, Virginia. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. EPA has also determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental Relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 60

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental Relations, Lead, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 264

Environmental protection, Air pollution control, Container, Control device, Hazardous waste, Monitoring, Reporting and recordkeeping requirements, Surface impoundment, Tank, Treatment storage and disposal facility, Waste determination.

40 CFR Part 265

Environmental protection, Air pollution control, Container, Control device, Hazardous waste, Monitoring, Reporting and recordkeeping requirements, Surface impoundment, Tank, Treatment storage and disposal facility, Waste determination.

Dated: March 21, 1997.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, parts 52, 60, 264 and 265 of chapter I of title 40 of the Code of Federal Regulations are proposed to be amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

Authority: 42 U.S.C. 7401–7671q.

Subpart VV—[Amended]

2. Subpart VV is amended by adding a new § 52.2454 to read as follows:

§ 52.2454 Prevention of significant deterioration of air quality for Merck & Co., Inc.'s Stonewall Plant in Elkton, Virginia

(a) *Applicability.*

(1) This section applies only to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, in Elkton, Virginia (''site').

(2) This section sets forth the prevention of significant deterioration of air quality preconstruction review requirements for the following pollutants only: carbon monoxide, nitrogen oxides, ozone (using volatile organic compounds as surrogate), particulate matter with an aerodynamic diameter less than 10 microns (PM–10), and sulfur dioxide. This section applies in lieu of § 52.21 for the pollutants identified in this paragraph as well as particulate matter; however, the preconstruction review requirements of § 52.21, or other preconstruction review requirements that the Administrator approves as part of the plan, shall remain in effect for any pollutant which is not specifically identified in this paragraph and is subject to regulation under the Act.

(b) *Definitions.* For the purposes of this section:

12-month rolling total for an individual pollutant or the total criteria pollutants, as specified in paragraph (d) of this section, is calculated on a monthly basis as the sum of all actual emissions of the respective pollutant(s) from the previous 12 months.

Act means the Clean Air Act, as amended, 42 U.S.C. 7401, *et seq.*

Completion of the powerhouse conversion means the date upon which the new boilers, installed pursuant to paragraph (g) of this section, are operational. This determination shall be made by the site based on the boiler manufacturer's installation, startup and shakedown specifications.

Permitting authority means either of the following:

(1) The Administrator, in the case of an EPA-implemented program; or

(2) The State air pollution control agency, or other agency delegated by the Administrator, pursuant to paragraph (o) of this section, to carry out this permit program.

Process unit means:

(1) Manufacturing equipment assembled to produce a single intermediate or final product, and

(2) Any combustion device.

Responsible official means:

(1) The president, secretary, treasurer, or vice-president of the business entity in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the business entity; or

(2) A duly authorized representative of such business entity if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

(i) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars); or

(ii) The authority to sign documents has been assigned or delegated to such

representative in accordance with procedures of the business entity.

Site means the contiguous property at Route 340 South, Elkton, Virginia, under common control by Merck & Co., Inc., and its successors in ownership, known as the Stonewall site.

(c) *Authority to issue permit.* The permitting authority may issue to the site a permit which complies with the requirements of paragraphs (d) through (n) of this section. The Administrator may delegate, in whole or in part, pursuant to paragraph (o) of this section, the authority to administer the requirements of this section to a State air pollution control agency, or other agency authorized by the Administrator.

(d) *Site-wide emissions caps.* The permit shall establish site-wide emissions caps as provided in this paragraph.

(1) *Initial site-wide emissions caps.* The initial site-wide emissions caps shall be based on the site's actual emissions during a time period, within five years of the date of permit issuance, which represents normal site operation. The permitting authority may allow the use of a different time period upon a determination that it is more representative of normal source operation. Actual site-wide emissions shall be calculated using the actual operating hours, production rates, and types of materials processed, stored, or combusted during the selected time period.

(i) *Total criteria pollutant emissions cap.* The permit shall establish a total criteria pollutant emissions cap (total emissions cap). The criteria pollutants included in the total emissions cap are the following: carbon monoxide, nitrogen oxides, ozone (using volatile organic compounds as surrogate), particulate matter with an aerodynamic diameter less than 10 microns, and sulfur dioxide.

(ii) *Individual pollutant caps.* The permit shall establish individual pollutant caps for sulfur dioxide, nitrogen oxides and PM–10.

(2) *Adjustments to the site-wide emissions caps.*

(i) The permit shall require that upon completion of the powerhouse conversion, the site shall reduce the site-wide emissions caps as follows:

(A) The total emissions cap shall be reduced by 20 percent from the initial site-wide emissions cap established pursuant to paragraph (d)(1)(i) of this section.

(B) The sulfur dioxide cap shall be reduced by 25 percent from the initial site-wide emissions cap established pursuant to paragraph (d)(1)(ii) of this section.

(C) The nitrogen oxide cap shall be reduced by 10 percent from the initial site-wide emissions cap established pursuant to paragraph (d)(1)(ii) of this section.

(ii) The permit may specify other reasons for adjustment of the site-wide emissions caps.

(e) *Operating under the site-wide emissions caps.*

(1) The permit shall require that the site's actual emissions of criteria pollutants shall not exceed the total emissions cap established pursuant to paragraph (d) of this section.

(2) The permit shall require that the site's actual emissions of sulfur dioxide, nitrogen oxides and PM–10 shall not exceed the respective individual pollutant cap established pursuant to paragraph (d) of this section.

(3) Compliance with the total emissions cap and individual pollutant caps shall be determined by comparing the respective cap to the 12-month rolling total for that cap. Compliance with the total emissions cap and individual pollutant caps shall be determined within one month of the end of each month based on the prior 12 months. The permit shall set forth the emission calculation techniques which the site shall use to calculate site-wide actual criteria pollutant emissions.

(4) *Installation of controls for significant modifications and significant new installations.*

(i) This paragraph applies to significant modifications and significant new installations. Significant modifications for the purposes of this section are defined as changes to an existing process unit that result in an increase of the potential emissions of the process unit, after consideration of existing controls, of more than the significance levels listed in paragraph (e)(4)(ii) of this section. Significant new installations for the purposes of this section are defined as new process units with potential emissions before controls that exceed the significance levels listed in paragraph (e)(4)(ii) of this section. For purposes of this section, potential emissions means process unit point source emissions that would be generated by the process unit operating at its maximum capacity.

(ii) The significance levels for determining significant modifications and significant new installations are: 100 tons per year of carbon monoxide; 40 tons per year of nitrogen oxides; 40 tons per year of sulfur dioxide; 40 tons per year of volatile organic compounds; and 15 tons per year of PM–10.

(iii) For any significant modification or significant new installation, the permit shall require that the site install, at the process unit, emission controls, pollution prevention or other technology that represents good environmental engineering practice in the pharmaceutical or batch processing industry, based on the emission characteristics (such as flow, variability, pollutant properties) of the process unit.

(f) *Operation of control equipment.* The permit shall require that the site shall continue to operate the emissions control equipment that was previously subject to permit requirements at the time of issuance of a permit pursuant to this section. This equipment shall be operated in a manner which minimizes emissions, considering the technical and physical operational aspects of the equipment and associated processes. This operation shall include an operation and maintenance program based on manufacturers' specifications and good engineering practice.

(g) *Powerhouse conversion.* The permit shall require that the site convert the steam-generating powerhouse from burning coal as the primary fuel to burning natural gas as the primary fuel and either No. 2 fuel oil or propane as backup fuel.

(1) The new boilers shall be equipped with low nitrogen oxides technology.

(2) The site shall complete the powerhouse conversion (completion of the powerhouse conversion) no later than 30 months after the effective date of the permit.

(h) *Monitoring, recordkeeping and reporting.*

(1) The permit shall set forth monitoring, recordkeeping, and reporting requirements sufficient to demonstrate compliance with the site-wide emissions caps. The monitoring, recordkeeping and reporting requirements shall be structured in a tiered system, such that the requirements become more stringent as the site's emissions approach the total emissions cap.

(2) At a minimum, the permit shall require that the site submit to the permitting authority semi-annual reports of the site-wide criteria pollutant emissions (expressed as a 12-month rolling total) for each month covered by the report. These reports shall include a calculation of the total emissions cap, as well as, the emissions of sulfur dioxide, nitrogen oxides, carbon monoxide, volatile organic compounds and PM–10.

(3) Any reports required by the permit to be submitted on an annual or semi-annual basis shall contain a certification by the site's responsible official that to his belief, based on reasonable inquiry, the information submitted in the report is true, accurate, and complete.

(4) Any records required by the permit shall be retained on site for at least five years.

(i) *Air quality analysis.* The permittee shall demonstrate, prior to permit issuance and on a periodic basis which shall be specified in the permit, that emissions from construction or operation of the site will not cause or contribute to air pollution in excess of any:

(1) maximum allowable increase or maximum allowable concentration for any pollutant, pursuant to § 165 of the Act;

(2) national ambient air quality standard or;

(3) other applicable emission standard or standard of performance under the Act.

(j) *Termination.*

(1) The permit may be terminated as provided in this paragraph for reasons which shall include the following, as well as any other termination provisions specified in the permit:

(i) If the Administrator or the permitting authority determines that continuation of the permit is an imminent and substantial endangerment to public health or welfare, or the environment;

(ii) If the permittee knowingly falsifies emissions data;

(iii) If the permittee fails to implement the powerhouse conversion pursuant to paragraph (g);

(iv) If the permittee receives four consent orders or two judgments adverse to the site arising from non-compliance with this permit in a five year period that are deemed material by the Administrator or the permitting authority; or

(v) If the total emissions cap is exceeded.

(2) In the event of termination, the Administrator or the permitting authority shall provide the permittee with written notice of its intent to terminate the permit. Within 30 calendar days of the site's receipt of this notice, the site may take corrective action to remedy the cause of the termination. If this remedy, which may include a corrective action plan and schedule, is deemed acceptable by the Administrator or the permitting authority (whichever agency provided written notice of its intent to terminate the permit), the action to terminate the permit shall be withdrawn. Otherwise, the permit shall be terminated in accordance with procedures specified in the permit.

(3) Termination of the permit does not waive the site's obligation to complete any corrective actions relating to non-compliance under the permit.

(k) *Inspection and entry.*

(1) Upon presentation of credentials and other documents as may be required by law, the site shall allow authorized representatives of the Administrator and the permitting authority to perform the following:

(i) Enter upon the site;

(ii) Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit;

(iii) Have access at reasonable times to batch and other plant records needed to verify emissions.

(iv) Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations required under the permit;

(v) Sample or monitor any substances or parameters at any location, during operating hours, for the purpose of assuring permit compliance or as otherwise authorized by the Act.

(2) No person shall obstruct, hamper, or interfere with any such authorized representative while in the process of carrying out his official duties. Refusal of entry or access may constitute grounds for permit violation and assessment of civil penalties.

(3) Such site, facility and equipment access, and sampling and monitoring shall be subject to the site's safety and industrial hygiene procedures, and Food and Drug Administration Good Manufacturing Practice requirements (21 CFR 210 and 211) in force at the site.

(l) *Transfer of ownership.* The terms of the permit are transferable to a new owner upon sale of the site, in accordance with provisions specified by the permit.

(m) *Permit issuance.* The permitting authority shall provide for public participation prior to issuing a permit pursuant to this section. At a minimum, the permitting authority shall:

(1) Make available for public inspection, in at least one location in the area of the site, the information submitted by the permittee, the permitting authority's analysis of the effect on air quality including the preliminary determination, and a copy or summary of any other materials considered in making the preliminary determination;

(2) Notify the public, by advertisement in a newspaper of general circulation in the area of the site, of the application, the preliminary determination, and of the opportunity for comment at a public hearing as well as written public comment;

(3) Provide a 30-day period for submittal of public comment;

(4) Send a copy of the notice of public comment to the following: theTAdministrator, through the appropriate Regional Office; any other State or local air pollution control agencies, the chief executives of the city and county where the site is located; any State, Federal Land Manager, or other governing body whose lands may be affected by emissions from the site.

(5) Provide opportunity for a public hearing for interested persons to appear and submit written or oral comments on the air quality impact of the site, the control technology required, and other appropriate considerations.

(n) *Permit modifications.* The permit shall specify the conditions under which the permit may be modified by the permitting authority. The permitting authority shall modify the permit in accordance with the procedures set forth in this paragraph.

(1) *Permit modifications that require public participation.* For any change that does not meet the criteria for an administrative permit modification established in paragraph (n)(2)(i) of this section, the permitting authority shall provide an opportunity for public participation, consistent with the provisions of paragraph (m) of this section, prior to processing the permit modification.

(2) *Administrative permit modification.*

(i) An administrative permit modification is a permit revision that:

(A) Corrects typographical errors;

(B) Identifies a change in the name, address, or phone number of any person identified in the permit, or provides a similar minor administrative change at the site;

(C) Requires more frequent monitoring, recordkeeping, or reporting by the permittee;

(D) Allows for a change in ownership or operational control of a source where the permitting authority determines that no other change in the permit is necessary, provided that a written agreement containing a specific date for transfer of permit responsibility, coverage, and liability between the current and new permittee has been submitted to the permitting authority.

(E) Updates the emission calculation methods specified in the permit, provided that the change does not also involve a change to any site-wide emissions cap.

(F) Changes the monitoring, recordkeeping or reporting requirements for equipment that has been shutdown or is no longer in service.

(G) Any other change that is stipulated in the permit as qualifying as an administrative permit modification,

provided that the permit condition which includes such stipulation has already undergone public participation in accordance with paragraph (m) of this section.

(ii) An administrative permit modification may be made by the permitting authority consistent with the following procedures:

(A) The permitting authority shall take final action on any request for an administrative permit modification within 60 days from receipt of the request, and may incorporate such changes without providing notice to the public, provided that the permitting authority designates any such permit revisions as having been made pursuant to this paragraph.

(B) The permitting authority shall submit a copy of the revised permit to the Administrator.

(C) The site may implement the changes addressed in the request for an administrative permit modification immediately upon submittal of the request to the permitting authority.

(o) *Delegation of authority.*

(1) The Administrator shall have the authority to delegate the responsibility to implement this section in accordance with the provisions of this paragraph.

(2) Where the Administrator delegates the responsibility for implementing this section to any agency other than a Regional Office of the Environmental Protection Agency, the following provisions shall apply:

(i) Where the delegate agency is not an air pollution control agency, it shall consult with the appropriate State and local air pollution control agency prior to making any determination under this section. Similarly, where the delegate agency does not have continuing responsibility for managing land use, it shall consult with the appropriate State and local agency primarily responsible for managing land use prior to making any determination under this section.

(ii) The delegate agency shall send a copy of any public comment notice required under paragraph (n) of this section to the Administrator through the appropriate Regional Office.

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. Section 60.1 is amended by adding paragraph (d) to read as follows:

§ 60.1 Applicability.

* * * * *

(d) *Site-specific standard for Merck & Co., Inc.'s Stonewall Plant in Elkton, Virginia.* (1) This paragraph applies only to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, in Elkton, Virginia (''site'').

(2) Except for compliance with 40 CFR 60.49b(u), the site shall have the option of either complying directly with the requirements of this part, or reducing the site-wide emissions caps in accordance with the procedures set forth in a permit issued pursuant to 40 CFR 52.2454. If the site chooses the option of reducing the site-wide emissions caps in accordance with the procedures set forth in such permit, the requirements of such permit shall apply in lieu of the otherwise applicable requirements of this part.

(3) Notwithstanding the provisions of paragraph (d)(2) of this section, for any provisions of this part except for Subpart Kb, the owner/operator of the site shall comply with the applicable provisions of this part if the Administrator determines that compliance with the provisions of this part is necessary for achieving the objectives of the regulation and the Administrator notifies the site in accordance with the provisions of the permit issued pursuant to 40 CFR 52.2454.

3. Section 60.49b is amended by adding paragraph (u) to read as follows:

§ 60.49b Reporting and recordkeeping requirements.

* * * * *

(u) *Site-specific standard for Merck & Co., Inc.'s Stonewall Plant in Elkton, Virginia.*

(1) This paragraph applies only to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, in Elkton, Virginia (''site'') and only to the natural gas-fired boilers installed as part of the powerhouse conversion required pursuant to 40 CFR 52.2454(g). The requirements of this paragraph shall apply, and the requirements of 40 CFR 60.40b through 60.49b shall not apply, to the natural gas-fired boilers installed pursuant to 40 CFR 52.2454(g).

(i) The site shall equip the natural gas-fired boilers with low nitrogen oxide (NO_X) technology.

(ii) The site shall install, calibrate, maintain, and operate a continuous monitoring and recording system for measuring NO_X emissions discharged to the atmosphere and opacity using a continuous emissions monitoring system or a predictive emissions monitoring system.

(iii) Within 180 days of the completion of the powerhouse conversion, as required by 40 CFR 52.2454, the site shall perform a stack test to quantify criteria pollutant emissions.

(2) [Reserved]

4. Section 60.112b is amended by adding paragraph (c), to read as follows:

§ 60.112b Standard for volatile organic compounds (VOC).

* * * * *

(c) *Site-specific standard for Merck & Co., Inc.'s Stonewall Plant in Elkton, Virginia.* This paragraph applies only to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, in Elkton, Virginia (''site'').

(1) For any storage vessel that otherwise would be subject to the control technology requirements of paragraph (a) or (b) of this section, the site shall have the option of either complying directly with the requirements of this subpart, or reducing the site-wide total criteria pollutant emissions cap (total emissions cap) in accordance with the procedures set forth in a permit issued pursuant to 40 CFR 52.2454. If the site chooses the option of reducing the total emissions cap in accordance with the procedures set forth in such permit, the requirements of such permit shall apply in lieu of the otherwise applicable requirements of this subpart for such storage vessel.

(2) For any storage vessel at the site not subject to the requirements of 40 CFR 60.112b (a) or (b), the requirements of 40 CFR 60.116b (b) and (c) and the General Provisions (Subpart A of this part) shall not apply.

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

1. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, and 6925.

Subpart AA—[Amended]

2. Section 264.1030 is amended by adding paragraph (d) to § 264.1030 to read as follows:

§ 264.1030 Applicability.

* * * * *

(d) The requirements of this subpart do not apply to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, Elkton,

Virginia, provided that facility is operated in compliance with the requirements contained in a Clean Air Act permit issued pursuant to 40 CFR 52.2454. The requirements of this subpart shall apply to the facility upon termination of the Clean Air Act permit issued pursuant to 40 CFR 52.2454.

3. Subpart BB is amended by adding paragraph (g) to § 264.1050 to read as follows:

§ 264.1050 Applicability.

* * * * *

(g) The requirements of this subpart do not apply to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, Elkton, Virginia, provided that facility is operated in compliance with the requirements contained in a Clean Air Act permit issued pursuant to 40 CFR 52.2454. The requirements of this subpart shall apply to the facility upon termination of the Clean Air Act permit issued pursuant to 40 CFR 52.2454.

4. Subpart CC is amended by adding paragraph (e) to § 264.1080 to read as follows:

§ 264.1080 Applicability.

* * * * *

(e)(1) Except as provided in paragraph (e)(2) of this section, the requirements of this subpart do not apply to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, Elkton, Virginia, provided that facility is operated in compliance with the requirements contained in a Clean Air Act permit issued pursuant to 40 CFR 52.2454. The requirements of this subpart shall apply to the facility upon termination of the Clean Air Act permit issued pursuant to 40 CFR 52.2454.

(2) Notwithstanding paragraph (e)(1) of this section, any hazardous waste surface impoundment operated at the Stonewall Plant is subject to:

(i) the standards in § 264.1085 and all requirements related to hazardous waste surface impoundments that are referenced in or by § 264.1085, including the closed-vent system and control device requirements of § 264.1087 and the recordkeeping requirements of § 264.1089(c); and

(ii) the reporting requirements of § 264.1090 that are applicable to surface impoundments and/or to closed-vent systems and control devices associated with a surface impoundment.

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

1. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, and 6937, unless otherwise noted.

2. Subpart AA is amended by adding paragraph (c) to § 265.1030 to read as follows:

§ 265.1030 Applicability.

* * * * *

(c) The requirements of this subpart do not apply to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, Elkton, Virginia, provided that facility is operated in compliance with the requirements contained in a Clean Air Act permit issued pursuant to 40 CFR 52.2454. The requirements of this subpart shall apply to the facility upon termination of the Clean Air Act permit issued pursuant to 40 CFR 52.2454.

3. Subpart BB is amended by adding paragraph (f) to § 265.1050 to read as follows:

§ 265.1050 Applicability.

* * * * *

(f) The requirements of this subpart do not apply to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, Elkton, Virginia, provided that facility is operated in compliance with the requirements contained in a Clean Air Act permit issued pursuant to 40 CFR 52.2454. The requirements of this subpart shall apply to the facility upon termination of the Clean Air Act permit issued pursuant to 40 CFR 52.2454.

4. Subpart CC is amended by adding paragraph (e) to § 265.1080 to read as follows:

§ 265.1080 Applicability.

* * * * *

(e)(1) Except as provided in paragraph (e)(2) of this section, the requirements of this subpart do not apply to the pharmaceutical manufacturing facility, commonly referred to as the Stonewall Plant, located at Route 340 South, Elkton, Virginia, provided that facility is operated in compliance with the requirements contained in a Clean Air Act permit issued pursuant to 40 CFR 52.2454. The requirements of this subpart shall apply to the facility upon termination of the Clean Air Act permit issued pursuant to 40 CFR 52.2454.

(2) Notwithstanding paragraph (e)(1) of this section, any hazardous waste surface impoundment operated at the Stonewall Plant is subject to the standards in § 265.1086 and all requirements related to hazardous waste surface impoundments that are referenced in or by § 265.1086, including the closed-vent system and control device requirements of § 265.1088 and the recordkeeping requirements of § 265.1090(c).

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