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Project XL Site-Specific Rulemaking for
Merck & Co., Inc. Stonewall Plant; Final
Rule

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 52, 60, 264 and 265**

[FRL-5905-3]

Project XL Site-specific Rulemaking for Merck & Co., Inc. Stonewall Plant**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: The EPA is implementing 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 Final Project Agreement (FPA) which is available in the docket for this action. In addition, EPA is promulgating today a site-specific rule, applicable only to the Merck Stonewall Plant, to facilitate implementation of the project.

This site-specific rule provides 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 site-specific rule changes the requirements under the Clean Air Act which apply to the Merck Stonewall Plant for the prevention of significant deterioration of air quality and certain new source performance standards. EPA also is promulgating a site-specific rulemaking under RCRA to provide regulatory changes pertaining to air emissions standards.

DATES: This rule is effective on October 8, 1997.

ADDRESSES: *Docket.* A docket containing supporting information used in developing this 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.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Moran, U.S. Environmental Protection Agency, Region III, Air,

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I. Authority

This regulation is being promulgated 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, and 3010 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act, as amended (42 U.S.C. 6905, 6912, 6921-6927, and 6930). 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 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

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.

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 site-specific rule supports a proposed permit and Project XL 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. On March 31, 1997, EPA published a notice of proposed rulemaking to seek public comment on the proposed site-specific rule. See 62 FR 15304-15322. In this notice, EPA also sought public comment on the proposed FPA and the project generally. At the request of the Southern Environmental Law Center, a public hearing was held on April 14, 1997, in Harrisonburg, Virginia. The comment period closed on May 15, 1997. EPA received 60 comment letters during the public comment period, and 8 comment letters after the close of the comment period. EPA's response to the key issues raised by commenters is contained in Section IV of this preamble. A separate Response to Comments Document, which fully addresses the comments, is contained in the docket for this action and is available on the world wide web at <http://www.epa.gov/ProjectXL>.

The FPA and proposed permit are contained in the docket for today's action and also are available on the world wide web at <http://www.epa.gov/ProjectXL>. The FPA outlines how the project addresses the Project XL criteria, in particular how the project will produce, measure, monitor, report, and demonstrate superior environmental benefits.

The Commonwealth of Virginia conducted the official comment period for the proposed PSD permit. The Commonwealth's public comment period for the proposed PSD permit and a proposed variance began on January 28, 1997, and closed on May 30, 1997. The VADEQ held a public hearing to solicit comment on the proposed permit and variance on February 27, 1997. The VADEQ plans to request the State Air Pollution Control Board (Board) to adopt the variance in the near future.

In the near future, EPA plans to delegate, with EPA oversight, the authority to implement and enforce the PSD site-specific rule (40 CFR 52.2454) to the Commonwealth of Virginia. This delegation would authorize the VADEQ to issue the PSD permit to Merck. The VADEQ expects to issue the PSD permit after the Board approves the variance, and after EPA's delegation of authority is effective.

2. Merck XL Project Description

The Merck XL project was described in detail in the preamble to the proposed site-specific rulemaking. See 62 FR 15305-15306 (March 31, 1997). The goal of the Merck XL project is to develop a regulatory structure for the Merck Stonewall Plant that both

facilitates flexible manufacturing operations and achieves superior environmental performance. Merck's XL project seeks to replace the current air 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 (SO₂), nitrogen oxides (NO_x), and particulate matter with an aerodynamic diameter less than 10 microns (PM₁₀). 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 SO₂ 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 SO₂ and NO_x by 25 percent and 10 percent, respectively.

Merck's XL project will be implemented through issuance of a site-wide PSD permit, authorized by this site-specific rulemaking. Under the site-specific rule and permit, the Merck Stonewall Plant will be required to maintain its emissions below the total emissions cap, as well as the subcaps for SO₂, NO_x and PM₁₀. Under the site-

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 (PM₁₀). 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 PM_{2.5} or new criteria pollutants which are not included in the total emissions cap.

wide emissions caps, changes or additions to facility operations would no longer need prior approval under PSD or NSR. The subcaps will keep SO₂ and NO_x emissions below recent actual emission levels and PM₁₀ 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 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. Certain criteria pollutants have been demonstrated to have a significant adverse effect on the environmental quality of the Shenandoah National

Park. In particular, SO₂ 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 SO₂ and NO_x also contribute to the formation of acid rain and associated adverse impacts. Merck's powerhouse conversion will achieve an up-front reduction of these pollutants—SO₂ 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 actual emission levels. After the powerhouse conversion, the total emissions cap and subcaps will 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 site-specific rulemaking and issuance of the PSD permit. See the preamble to the proposed site-specific rule (62 FR 15309–15312, March 31, 1997).

III. Summary of Regulatory Requirements for the Merck XL Project

A. Clean Air Act

The alternate regulatory system that is established under this site-specific rule and the 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.

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 today's rule is limited to the Merck Stonewall Plant and should not be interpreted as a more general revision of regulations, or even as initiating a process toward such a general revision.

1. Prevention of Significant Deterioration

In today's action, EPA is promulgating a site-specific PSD rule for the Merck Stonewall Plant in order to implement the XL project for the site. See 40 CFR 52.2454. This site-specific rule replaces (in most circumstances) the existing PSD rules at 40 CFR 52.21 for the Merck Stonewall Plant only, and establishes the legal authority to issue the PSD permit to the Merck Stonewall Plant. The site-specific PSD requirements were described in detail in the preamble to the proposed rulemaking. See 62 FR 15309–15312 (March 31, 1997).

The Merck Stonewall Plant is located in an area that currently 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. The 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 SO₂, NO_x, PM₁₀, 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 52.21,³ for the control of lead emissions, PM_{2.5},⁴ and any new criteria pollutants promulgated by EPA. If in the future EPA were to promulgate standards for other forms of fine particulates (e.g., PM_{1.0}), Merck also would be required to comply directly with any associated

³The Commonwealth of Virginia currently implements 40 CFR 52.21 under a delegation of authority from EPA. See 40 CFR 52.2451.

⁴Particulates with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers.

applicable requirements. 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).⁵

Merck will be allowed to vary its emission levels under the total emissions cap, constrained by the individual pollutant subcaps. Changes at the facility that might otherwise 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 SO₂ and NO_x emissions well below recent actual emissions. The emission limitations for PM₁₀ 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 are satisfied pursuant to this site-specific rulemaking.

The site-specific PSD rule (40 CFR 52.2454) is being promulgated as proposed, with the exception of a clarification that the site-specific rule does not apply in lieu of the PSD regulations at 40 CFR 52.21 for PM_{2.5}. See 40 CFR 52.2454(a)(2). This revision to the final rule is described further in Section IV.C.3 of this preamble. In response to public comments, the proposed PSD permit has been changed to address issues regarding requirements for the control of PM_{2.5}, RCRA hazardous waste accumulation and/or storage vessels, and monitoring device data availability. These issues and associated permit changes are described in sections V.C, VI, and VIII.D, respectively, of the Response to Comments Document (contained in the docket and on the world wide web at <http://www.epa.gov/ProjectXL>).

2. New Source Performance Standards

EPA also is promulgating a site-specific rule which establishes an alternative means of compliance for the Merck Stonewall Plant for two New Source Performance Standards (NSPS)—

⁵ 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 extends 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 PM₁₀ as the regulated form of particulate matter for purposes of PSD applicability; however, this rulemaking does not extend the policy to PM_{2.5}.

Subpart Db (Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units) and Subpart Kb (Standards of Performance for Volatile Organic Liquid Storage Vessels). See 40 CFR 60.1(d); 40 CFR 60.49b(u); and 40 CFR 60.112b(c). For NSPS other than Subpart Kb that may become applicable to the site in the future, EPA is promulgating 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 NSPS alternative means of compliance is described in detail in the preamble to the proposed site-specific rulemaking. See 62 FR 15314–15315 (March 31, 1997).

The NSPS site-specific rule is being promulgated as proposed, with the exception of a correction to a citation. In 40 CFR 60.49b(u)(1) (pertaining to alternate compliance for the new natural gas-fired boilers), EPA has corrected an error in the citation contained in the proposed rule such that the second sentence now reads, "The requirements of this paragraph shall apply, and the requirements of 40 CFR 60.40b through 60.49b(t) shall not apply, to the natural gas-fired boilers installed pursuant to 40 CFR 52.2454(g)." The proposed rule cited 40 CFR 60.49b, rather than 40 CFR 60.49b(t), which would have mistakenly included as not applicable the new paragraph 40 CFR 60.49(u).

3. State Implementation Plan Requirements

On January 28, 1997, VADEQ requested 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 the near future. 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

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

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 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. For a further description of Merck's compliance with SIP requirements under this XL project, see the preamble to the proposed site-specific rule (62 FR 15313, March 31, 1997).

B. Resource Conservation and Recovery Act

In addition to Clean Air Act requirements, today EPA also is establishing alternate regulatory requirements for the RCRA air emission standards for the Merck Stonewall Plant. 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. Under this XL Project, the hazardous waste management units at the Merck Stonewall Plant that would otherwise be subject to those 40 CFR parts 264 and 265 standards will be regulated through an enforceable PSD permit and a preventive maintenance program. See 62 FR 15315 (March 31, 1997).

For hazardous waste tanks and containers located at the Merck Stonewall Plant, the proposed 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, today's site-specific regulation will exempt the Merck Stonewall Plant from the administrative requirements of the RCRA air standards; the proposed PSD permit and a future 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. See 40 CFR 265.1080(b)(7); 61 FR 59971 (November 25, 1996). 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 facility'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 Agency continues to consider the requirements contained in the proposed PSD permit to be a viable approach to addressing organic air emission from hazardous waste units at the Merck Stonewall Plant. Therefore, the site-specific exemption from requirements of 40 CFR parts 264 and 265 is being finalized today exactly as it was proposed. See 62 FR 15303 (March 31, 1997). The Response to Comments Document describes a change to the proposed PSD permit that was made to address a commenter's question about the permit requirements for RCRA hazardous waste accumulation and/or storage vessels. This comment and the associated change to the proposed PSD permit are described in Section VI of the Response to Comments Document (contained in the docket).

IV. Summary of Response to Key Public Comments

EPA received 60 comment letters on the proposed Merck XL project during the public comment period. An additional eight comment letters were received after the close of the comment period. These letters primarily reflected comments similar to those received during the comment period; therefore, EPA's response to comments generally addresses issues raised in the late comments as well. In the following section, the Agency responds to several of the key issues raised by commenters. A comprehensive response to comments is contained in a separate document, "Merck XL Site-Specific Rulemaking—Response to Comments Document" which is contained in the docket and available on the world wide web at <http://www.epa.gov/ProjectXL>.

A. General Support of Project

General support for the Merck XL project was expressed by several citizens, government officials, industry associations, state environmental agencies, businesses, and the Merck workers union. Several citizens commented that Merck is a good environmental steward and a good corporate neighbor. Some commenters expressed that, besides the project's immediate benefits to environmental quality in the area, the project will further benefit the community by making the Stonewall Plant more attractive as a site for product expansion and new product introduction, resulting in increased employment opportunities for people living in the Shenandoah Valley. Many comments also supported the simplified regulatory process and increased operational flexibility afforded to Merck. Two state environmental agencies commented that the project is an excellent example of innovative permitting, and commended EPA for its efforts. These states believe that the project is a great example of EPA's reinventing environmental regulation initiative, and will provide significant environmental performance while allowing Merck the flexibility warranted by such a permit. One state added that it supports the permit's strong incentives to minimize air emissions of criteria pollutants on an ongoing basis. Industry associations and companies commented that the project will benefit future permitting strategies that seek better ways to protect the environment. A Virginia industry association urged EPA to advance the project to the implementation stage where the value of the increased

operational flexibility can be clearly demonstrated.

B. Superior Environmental Performance

1. General

Numerous commenters, including citizens, environmental groups, state environmental agencies, industry groups, and political officials, expressed support for the emission reductions that will be achieved by Merck converting its coal-fired boilers to burn natural gas. Many of the citizen and environmental group commenters supported the permanent reduction of criteria air pollutants by 300 TPY, as well as the upfront reduction of criteria pollutants by 900 TPY, and of hazardous air pollutants by 47 TPY. These comments specifically addressed the importance of this project's environmental benefits to Shenandoah National Park. A citizen commenter added support for the other positive elements of the project, including the provision that the project does not allow the sale or acquisition of emission credits, and that annual or semi-annual reports must be submitted to the project signatories.

2. Level of Emissions Caps

There were some comments from environmental groups and a citizen regarding the level of reduction of certain emission caps from the baseline levels. One environmental group questioned why the site-wide total emissions cap was set at a level of 20% less than recent actual emissions when there will be a 60% emissions reductions of criteria pollutants from the replacement of coal-fired boilers.

The baseline for the site-wide emissions cap is the average of annual actual emissions during the years 1992–93 (approximately 1500 TPY), the recent years most representative of normal facility operations. See 62 FR 15309 (March 31, 1997). Detailed information about the establishment of the emissions caps is contained in the rulemaking docket. The site-wide emissions cap will be reduced by 20% from the baseline level (i.e., the reduced cap level will be 1200 TPY, thereby permanently retiring 300 TPY of emissions) after the powerhouse conversion. Thus, Merck's new "allowable" emissions (the cap) will be 20% lower than recent actual emissions. In fact, Merck's allowable emissions in the baseline period were approximately 2700 TPY, so its new allowable emissions (i.e., the total emissions cap) will be less than half of the old allowable limit. The only reason that Merck is able to reduce its baseline cap by 20% is because of the significant actual emission reductions that will be

achieved from the powerhouse conversion (switching from burning coal to natural gas, a much cleaner burning fuel). The powerhouse conversion will reduce criteria pollutant emissions by approximately 900 TPY, bringing post-conversion site-wide actual criteria pollutant emissions to approximately 600 TPY (i.e., 1500 TPY minus 900 TPY). With the 20% cap reduction, Merck's "margin for growth" under the cap will be approximately 600 TPY (i.e., 1200 TPY minus 600 TPY). If the cap were set at the facility's post-powerhouse conversion level, as suggested by the commenter, Merck would have no operating margin for growth, and, thus, no incentive to enter into this project or implement the powerhouse conversion. In order to provide the regulatory and operational flexibility of this XL project, it is necessary to have an adequate margin for growth under the cap. EPA anticipates that Merck's emissions will remain far below the total emissions cap for a long period of time after the powerhouse conversion, in part because the tiered monitoring system provides an incentive to minimize emissions.

As long as Merck operates under this PSD permit, Merck will no longer be able to obtain permits to increase emissions above the cap, since an exceedance of the total emissions cap is a basis for termination of the permit. Under the current permitting system, Merck would not be constrained by a site-wide emissions cap, and could continue to increase emissions as long as the proper permits were obtained.

Another environmental group commenter supported the overall permanent emission reductions that will be achieved (300 TPY), but expressed concern about the volatile organic compound (VOC) emission increases allowed under the cap. The commenter expressed concern that while NO_x emissions will initially decrease, the permanent reduction assured is only 29 TPY (i.e., a 10% reduction of the NO_x subcap from baseline emissions); meanwhile, VOC emissions can increase substantially above current levels. The commenter believes that, given that both NO_x and VOC emissions contribute to ozone formation, Merck's contribution to ozone formation could increase rather than decrease over time. The commenter suggests that a lower NO_x cap could correct this problem. Alternatively, Merck commented that the setting of the individual emission caps was the subject of extensive debate during the stakeholder meetings, and that the levels prescribed in the proposed permit are the result of full agreement from the stakeholder group. Merck stated that it

is not aware of any new and compelling information to substantiate any need for changes to the emission caps.

EPA does not believe there is a need to set a lower NO_x cap. The impact of the potential VOC emission increases under the cap on ozone formation is described elsewhere in this document and in the preamble to the proposed site-specific rulemaking. See 62 FR 15310 (March 31, 1997). Merck's NO_x emissions cap guarantees that its future actual NO_x emissions will always be at least 10% less than recent actual emissions. Further, Merck's current permitted NO_x emissions are 569 TPY; thus, by taking a NO_x cap at a level that is 10% less than current actual emissions (i.e., 262 TPY), Merck also is relinquishing the ability to emit NO_x at the currently permitted levels. In the preamble to the proposed site-specific rulemaking, EPA described an analysis (contained in the docket) that had been conducted to demonstrate that Merck's worst-case VOC emissions would continue to provide protection of the ozone NAAQS. See 62 FR 15310 (March 31, 1997). Because this analysis demonstrates that Merck's worst-case VOC emissions will continue to provide protection of the ozone NAAQS, and because Merck's worst-case NO_x emissions will be less than recent emissions, EPA does not believe that Merck's contribution to ozone formation under this project would increase rather than decrease over time, compared to Merck's current emissions levels and its ability to increase emissions under the current permitting system. Therefore, EPA does not agree that it is necessary to establish a lower NO_x subcap.

3. Volatile Organic Compound (VOC) Emissions

Several citizens and environmental groups expressed concern about the potential increase in VOC emissions from recent levels, as Merck operates under the site-wide emissions cap. Some commented that since there is no specific cap on VOC emissions, Merck would be able to increase VOCs by about 650 TPY from recent emission levels. One citizen commented on the tradeoff of VOCs and CO for reductions in other pollutants, and questioned the value of that tradeoff and whether there is a way to measure it. Some commenters believed that since VOCs are a major source of ozone, the potential VOC increases would have a detrimental effect on respiratory health, the health of the forests in Shenandoah National Park and elsewhere, tourism, and crop yields.

As Merck operates under the total emissions cap, it is permissible over

time for VOC emissions to increase above the baseline VOC levels. The baseline VOC emission level is 408 TPY. If all other pollutants remain at their expected post-powerhouse conversion levels, the maximum VOC emissions increase (above baseline VOC emissions level) under the cap would be approximately 650 TPY. It should be noted that if Merck were to increase VOC emissions by this amount it would no longer have a margin for growth under the site-wide emissions cap and would have to implement the most stringent tier of monitoring, recordkeeping and reporting. Thus, Merck has an incentive not to reach this level of emissions. Nevertheless, an analysis was conducted to determine the impact on the ozone NAAQS if Merck were to increase VOC emissions to the maximum amount under the cap. In the preamble to the proposed site-specific rulemaking, EPA described an analysis (contained in the docket) that had been conducted to demonstrate that Merck's worst-case VOC emissions would continue to provide protection of the ozone NAAQS. See 62 FR 15310 (March 31, 1997).

The Merck Stonewall Plant is located in an area that is NO_x-limited for ground-level 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 NO_x 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 increased 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. See 62 FR 15310 (March 31, 1997) and the docket. In summary, this report analyzed a worst case scenario which showed that the expected ozone increase from Merck's potential VOC emissions would be less than 0.5 parts per billion (ppb), which is less than 0.5% of the 120 ppb ozone standard, and 0.625% of the 80 ppb ozone standard. EPA believes that the analysis portrayed a highly conservative worst case scenario and that the potential ozone formation would be negligible under actual conditions. Moreover, the NO_x emission reductions achieved as a result of Merck's powerhouse conversion and the establishment of

permanent NO_x subcaps will 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.

Other commenters stated that the permit's review structure would put severe limitations on incorporating any future knowledge about VOCs into the permit's conditions. One citizen commenter suggested that Merck should be required to contribute to an EPA-approved study of the contribution of VOCs to air pollution. This commenter expressed the need to study the effects of the various chemicals that will be emitted on the natural, historic and human resources of the Shenandoah area.

The proposed PSD permit has numerous provisions that were designed specifically to address the effects of Merck's VOC emissions. Any future knowledge about the environmental or public health effects of VOCs will be implemented in the Merck permit in the following ways. First, Merck will be required to comply with any generally applicable future regulation designed to control VOCs, and generally would have the option to reduce the cap in lieu of directly implementing the regulation (Section 1.2.2 of the permit). Second, Merck will conduct an assessment of VOC emissions for impacts on air quality related values (AQRVs) in Shenandoah National Park if VOC emissions reach specified levels. See Section 6.2.1 of the permit. Third, Merck is required to comply directly with any requirements for the control of hazardous air pollutants (HAPs), including the forthcoming maximum achievable control technology (MACT) standard for the pharmaceutical industry. Compliance with the pharmaceutical MACT and other HAP requirements also will control VOC emissions, because some of the HAPs used or emitted by Merck are also VOCs. Finally, 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). If this modeling assessment predicts an exceedance of the Significant Ambient Air Concentrations (SAAC), which are based on a fraction of the Threshold

Limit Values⁷, Merck must either demonstrate that the site's emissions produce no endangerment to human health, or implement changes at the site resulting in ambient concentrations that are below the SAAC or that are otherwise acceptable to VADEQ. This permit provision (Section 6.2.2) was developed to address the community stakeholders' concerns about the potential public health effects of Merck's VOC emissions. Because the AQRV assessment and the non-HAP VOC public health assessment are actions that will happen at some future point in time, if Merck reaches the respective VOC trigger levels, the permit provides for any new information about VOCs to be considered at the time the assessments are conducted. Similarly, any future regulations promulgated to control VOC emissions will take into account the latest information about the effects of VOCs.

While the Merck project does not require that the permit be reopened to factor in new information about VOCs, the project offers an important opportunity for stakeholders to raise issues of concern to be considered at the five-year permit reviews. It is important to note that the generally applicable PSD regulations do not require that permits be reopened to incorporate future knowledge about emissions information. So long as a permittee complies with the emission limitations and other permit terms, and does not make changes at the facility that require further permitting review, the permit would not be required to be reopened to incorporate future information about the permitted emissions levels.

EPA does not agree that it is necessary under Project XL for Merck to contribute to an EPA-approved study of the contribution of VOCs to air pollution. There are already a number of efforts under way to assess the various public health and environmental effects of VOC emissions. For years, the Ozone Transport Assessment Group (OTAG) has undertaken region-wide studies of the effects of VOCs on ozone formation. Under Section 112(b)(2) of the Clean Air Act, EPA is required to periodically review the list of HAPs to add pollutants which may present a threat of adverse human health effects. As for all HAPs, if any new VOCs are added to the list of HAPs, Merck will be required to control them in accordance with the applicable HAP requirements.

⁷ Threshold Limit Values, established for many chemicals, are workplace limits based on chronic and acute health effects, and are listed in the American Conference of Governmental Industrial Hygienists handbook.

4. PM-10 Emissions

A citizen commented that there is no PM₁₀ environmental benefit in this project, and that even a little benefit would be appreciated. Merck commented that the powerhouse conversion from coal to natural gas is estimated to result in a PM₁₀ emissions decrease of 74,000 pounds per year (37 TPY), which is a 98% reduction from baseline actual PM₁₀ emissions. Merck stated that the PM₁₀ cap was set at a level that reflects the lack of accurate PM₁₀ emission factors and already very low PM₁₀ emission rates at the plant. Merck commented that no new and compelling information has been presented to indicate a change to the PM₁₀ cap is warranted.

The permit establishes a PM₁₀ subcap at the baseline emissions level of 42 TPY. The PM₁₀ subcap will not be reduced after the powerhouse conversion. However, as Merck's comment indicates, the project will result in an upfront reduction of a substantial amount of PM₁₀, from the burning of natural gas instead of coal. During the stakeholder discussions in developing this project, Merck had repeatedly expressed concern about setting a PM₁₀ subcap at a level that would unnecessarily restrict future growth of operations, when there might be plenty of room for expansion of total emissions under the site-wide cap. In other words, because the baseline PM₁₀ emissions were already relatively low (42 TPY), a "reduced" PM₁₀ cap, similar to that for SO₂ and NO_x, could be the limiting factor in whether Merck would be able to expand operations in the future. That scenario would be counter to this XL's project's goal of providing increased operational flexibility. The ambient air quality modeling for PM₁₀ conducted in support of the proposed permit demonstrated that the site's current worst-case emission rates do not cause or contribute to a violation of the NAAQS. See 61 FR 15310 (March 31, 1997). The permit further provides for Merck's ambient impact, which will include impacts of the PM₁₀ emissions, to be reevaluated at each five-year review period. Thus, EPA believes that the level of the PM₁₀ emissions cap established in the permit is appropriate.

C. National Ambient Air Quality Standards (NAAQS)

1. Future Nonattainment Situation

Two companies located in the Rockingham County, Virginia, area submitted comments regarding the potential for the area to become nonattainment for ozone or other pollutants in the future, and expressed

concern for the impact of possible additional nonattainment control strategies on other sources in the area. Under the new PSD permit, Merck would be required to comply with any new criteria pollutant regulations, including those that might be promulgated if the area becomes a nonattainment area in the future; however, Merck generally would have the option to comply with the new regulations via a cap reduction. See Section 1.2.2 of the proposed PSD permit. In the preamble to the proposed rulemaking, EPA explained that the Commonwealth of Virginia could not take emissions reduction credit in an attainment plan if Merck chooses the option of reducing its emissions caps, rather than complying directly with a criteria pollutant regulation. See 62 FR 15313 (March 31, 1997). These companies are concerned that they would be required to implement stricter controls, at greater cost, because Merck's cap reduction would not be credited for attainment planning purposes. The commenters do not believe that sources should have to make up for the actual emission reductions because of the insulation provided to Merck. One company suggested that EPA should allow it to have the same insulation since its actual emissions are considerably lower than its permitted emissions.

Merck commented that it believes there is confusion about the possibility of more stringent future control requirements for other nearby facilities under a regional RACT plan as a result of this project. Merck described its view of the events which would have to occur before other nearby facilities would be impacted by more stringent controls, which it believes is an unlikely situation. Merck also submitted additional technical information prepared by a consultant relating to Merck's impact on local air quality and the implications of the new proposed ozone NAAQS.

The area in which the Merck facility is located has been well documented to be NO_x limited for ozone formation. Therefore, it is most likely that, if the area became nonattainment for the ozone NAAQS in the future, a control strategy would predominantly target reductions in NO_x emissions, rather than VOC emissions. In the preamble to the proposed rule, EPA described an analysis which documented that the worst-case potential VOC emissions under Merck's cap would continue to provide protection of the ozone NAAQS. See 62 FR 15310 (March 31, 1997).

The planning involved in designing a control strategy to bring an area into attainment is based on an inventory of actual emissions. Since Merck will achieve significant actual emission reductions of NO_x from the powerhouse conversion, these low actual NO_x emissions will help to reduce ozone formation and will benefit any future control strategy efforts. In a sense, it could be viewed that Merck is complying "early" with any future actual NO_x emission reductions that might be required for nonattainment planning. Similarly, other sources in the area which have very low actual emissions (e.g., as a result of BACT or comparable technology) likely would not be targeted for additional controls for those well-controlled and low-emitting units. Rather, nonattainment control strategies typically target those sources (both stationary and mobile sources) which are capable of achieving substantial decreases in actual emissions.

2. Ozone NAAQS—General

An environmental group commented that the forests of Virginia are already suffering as a result of both ozone and acid ion deposition, and suggested that this information should be documented. The commenter provided information about the rate of decline of oak forests in the northern mountains of Virginia.

EPA agrees with the commenter that ozone is a cause of degradation to forests and other vegetation in the Shenandoah area. The proposed Final Project Agreement describes the adverse effects of ozone and other pollutants on resources in the Park. The rulemaking docket includes a copy of the U.S. Department of Interior's Preliminary Notice of Adverse Impact on Shenandoah National Park (55 FR 38403, September 18, 1990) and the accompanying Technical Support Document. These documents explain the potential impacts of ozone, NO_x, and SO₂ on forests and vegetation, as well as potential impacts of pollutants on aquatic streams and visibility.

A commenter from a company in Rockingham County commented that there is no scientific evidence presented in the preamble to the site-specific rulemaking or background documents that Rockingham County is a NO_x-limited area for ozone. The commenter also suggested that EPA require baseline air quality monitoring in Rockingham County to specifically address the importance of VOCs in relation to ozone transport.

It has been well documented that the area in which the Merck Stonewall Plant is located is NO_x-limited for

ozone formation.⁸ The Permit Support Document (contained in the docket) includes additional information and references that the area is NO_x-limited. The OTAG modeling effort of ozone in the eastern U.S. is one of the largest public-private air quality projects ever conducted. As part of its key modeling findings related to future attainment strategies, OTAG found that NO_x emission reductions are more effective than VOC emission reductions in lowering regional ozone concentrations; NO_x reductions decrease ozone domain wide, while VOC reductions decrease ozone only in urban areas. A copy of this modeling report is contained in the docket. In its public comments, Merck submitted additional technical papers for the docket that document that the area is NO_x-limited for ozone formation.

The PSD requirement for pre-construction ambient air quality monitoring has been satisfied. The docket contains the ambient ozone monitoring data that satisfies this requirement. EPA disagrees that additional monitoring should be required within the context of the Merck XL project to address the importance of VOCs in ozone transport. These efforts are being undertaken in a much broader context by the OTAG modeling studies. Further, ozone transport is a regional issue and it is currently not feasible to study the effects of VOC from a single source on ozone transport.

3. New Ozone and Particulate Matter NAAQS

Several environmental groups and citizens requested EPA to address how Merck would comply with the new proposed NAAQS for ozone and fine particulates. Some commenters expressed concern that they believe the permit does not account for EPA's proposed new air quality standards, and allows a long term escape from higher standards, especially particulates. Some commenters also believe the permit should be reconsidered to account for PM_{2.5}.

On July 18, 1997, EPA promulgated final rules which revise the NAAQS for ozone (62 FR 38855-38896) and particulate matter (62 FR 38651-38752). Under EPA's final rule, the NAAQS for particulate matter is revised in several respects, including the addition of two new standards for PM_{2.5} (particulates with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers). Because PM_{2.5} (fine particulates) is a

⁸ Ozone Transport Assessment Group, Modeling Report (Draft), Regional and Urban Scale Modeling Workgroup, Version 1.1., February 12, 1997 (contained in docket).

new indicator for particulate matter, PM_{2.5} is not one of the pollutants specifically included in Merck's site-wide emissions cap.⁹ Rather, Merck would be required to comply directly with any future requirements for the control of PM_{2.5}. At the present time, EPA believes this is the more environmentally protective and scientifically sound approach, since no baseline data are available about Merck's PM_{2.5} emissions, methods to measure and monitor PM_{2.5} are not yet widely available, and it would be speculative to attempt to regulate PM_{2.5} as part of the site-wide emissions cap. Moreover, it will likely be several years before states have enough monitoring information available to know whether areas are not attaining the PM_{2.5} standard, and, consequently, whether and what type of PM_{2.5} control strategies are needed in a given area to bring an area into attainment. It should be noted that sulfates and nitrates are major components of secondary fine particles, formed in the atmosphere through chemical reactions. Therefore, the SO₂ and NO_x reductions from Merck's powerhouse conversion will help to reduce fine particulates.

The proposed site-specific rule (40 CFR 52.2454(a)(2)), stated that the rule applies in lieu of 40 CFR 52.21 for the pollutants included in the site-wide emissions cap, as well as particulate matter. In the final site-specific rule, EPA is adding language to ensure that it is clear that the rule does not apply in lieu of 40 CFR 52.21 for particulate matter specifically regulated as PM_{2.5}.

This change makes clear that the site-specific rule replaces 40 CFR 52.21 for particulate matter and PM₁₀, but not for particulate matter that is specifically regulated as PM_{2.5}. Similar changes also will be made in the final PSD permit to ensure that it is clear that the project does not provide alternate compliance for particulate matter specifically regulated as PM_{2.5}. If in the future EPA were to promulgate standards for other forms of fine particulates (e.g., PM_{1.0}), Merck also would be required to comply directly with any associated applicable requirements.

Under EPA's revision of the ozone NAAQS, ozone is not considered a new criteria pollutant. Rather, EPA revised the existing NAAQS for ozone to a lower and more protective standard. The regulated precursors for ozone formation, VOC and NO_x, are included in Merck's site-wide emissions cap. Therefore, Merck must comply with any

new regulations for the control of VOC or NO_x (ozone precursors) as prescribed by Section 1.2.2 of the permit. Under these provisions, Merck generally will have the option to reduce the site-wide total emissions cap (for VOC regulations) or NO_x subcap (for NO_x regulations), in lieu of implementing the regulation as written. This approach was described in detail in the preamble to the proposed rulemaking for the Merck XL project (61 FR 15313, March 31, 1997).

D. Public Participation Issues

1. Summary

Some commenters expressed concern about continuing community involvement in the permit. Related concerns include the unlimited term of the PSD permit, the composition of the decision-making group, and community input into decisions involving potential increases to the emissions levels of the permit. These issues are addressed substantively and thoroughly in this preamble and the Response to Comments Document.

EPA strongly supports ongoing community involvement in permit issues associated with this XL project. Many commenters remarked on the unprecedented level of participation this project has afforded the community thus far. The participation of Rockingham County as a signatory will assist in maintaining the level of community involvement during implementation. EPA also pledges to seek out and strongly weigh community and public interest group input and involvement where permit modifications or reviews are being considered. Stakeholders will be expressly included in the five-year reviews scheduled as a result of this project, affording public input opportunities on issues outside the scope of existing permit programs.

PSD permits are analogous to building permits, which are not normally revocable or subject to end dates. Thus, while this project offers Merck flexibility in the scope of the PSD permit, it does not offer Merck flexibility in terms of duration that it would not otherwise receive. EPA believes that the level of accountability contained in the proposed permit and the five-year reviews offer adequate oversight opportunity to both regulators and the community. These five-year reviews themselves are an additional step to ensure the protection of public health and the environment, and offer the stakeholders a role in the implementation of the permit. EPA commits to making any necessary

technical assistance or facilitation available to the stakeholders during the five-year review to ensure their informed participation.

The signatories to the Final Project Agreement (EPA, U.S. Department of the Interior/Federal Land Manager, Virginia Department of Environmental Quality, the Rockingham County Board of Supervisors, and Merck) generally must agree to any permit modifications that might be considered. During negotiations, the County was put forward as a signatory as a way of incorporating a representative vote for the community. The County, State, U.S. Department of the Interior, and EPA, as governmental entities, will ensure public support for any changes that go forward. If increases in the emissions caps are contemplated, EPA generally must amend the site-specific rule to propose changes to the permit. Although EPA fully expects that such increases in the emissions caps will not be necessary and therefore will not be proposed, EPA commits that, in any such instance, it will seek out and strongly consider the input of the community.

EPA would also like to note that, as described in Sections III.A.2, III.A.3, and IV.C above, this rule and the PSD permit require Merck to comply with future relevant regulatory changes or new standards that would otherwise apply to the facility.

Community involvement is and will continue to be critical to the success of Project XL. The Merck project was, in many ways, shaped by the input of the stakeholder group associated with the project. For example, Merck's original project proposal was greatly improved during the stakeholder process by addressing many stakeholder concerns, including a 20% decrease of the total emissions cap after the powerhouse conversions, emissions subcaps for PM₁₀, SO₂ and NO_x, strict compliance with all hazardous air pollutant (HAP) requirements, modeling of non-HAP VOC emissions to ensure protection of public health, assessment of VOC impacts in Shenandoah National Park, and several other provisions. EPA believes that the project as it is now reflected in the proposed PSD permit, the Final Project Agreement and the site-specific rule will enhance the community's opportunity for meaningful involvement in the implementation of the Merck XL project.

2. Permit Term

EPA received numerous comments from citizens and environmental groups supporting a limit on the term of the

⁹However, Merck will be required to include emissions of PM_{2.5} (as a subset of PM₁₀) in its calculation of PM₁₀ emissions.

PSD permit. Some commenters suggested that a limited permit term be established, after which the permit could be "affirmatively renewed" or renegotiated within some set of preestablished guidelines. Most of these commenters supported an initial permit term of 10–15 years, and one environmental group suggested a five year term. Another environmental group suggested an initial permit term reasonably sufficient to allow Merck to recover its investment in the boiler conversion, after which the permit could be affirmatively renewed on a five-year basis. One environmental group maintained that the unlimited permit term is unwise because the permit allows substantial VOC increases and there is currently inadequate information regarding the impacts of the VOC emission increases on human health and the Shenandoah National Park. One commenter believes that no other XL project has a permit with unlimited duration and a provision for veto of any changes by the applicant, and believes that this permit would establish an inappropriate precedent for these conditions.

Merck commented that the decision to craft the permit under PSD and include extensive review and termination procedures (Sections 6 and 8) was the compromise worked out among the stakeholders. Merck expressed that, absent new, compelling information from commenters on this issue they believe that EPA must act in good faith and decline any changes with regard to permit expiration.

In response, EPA notes that the "unlimited term" of the permit is consistent with the normal practice for PSD permits. They are permits to construct or modify a source, and are analogous to building permits which would not normally be revocable or have an end date. Once a source is permitted to construct the emission units authorized by the permit, so long as it complies with the permit's emission limitations and operational conditions, a source generally is not required to renew the PSD permit for those units. Under the particular circumstances presented in the Merck project, including the innovative emissions cap-based permit and Merck's substantial voluntary investments to achieve significant emission reductions, EPA believes it is appropriate to treat the entire set of changes authorized at the facility by this rule and the PSD permit as a single major modification. Because Merck's permit will be issued as a PSD permit, under a new site-specific PSD rule which applies only to the Stonewall Plant, EPA believes it is

consistent with the PSD program not to establish a term limit for Merck's permit. As a related issue, there currently are no specific Federal regulations for modifying PSD permits. If EPA in the future should promulgate permit modification rules that generally apply to PSD permits, Merck's permit would be subject to those permit modification procedures as well (Section 6 of the permit). In addition, the Merck permit goes beyond typical PSD permits by requiring a five-year periodic review and setting forth provisions for revising the permit. (See Section IV.D.3.b of this preamble for a more detailed discussion of the five-year review process). Therefore, EPA believes an unlimited term is warranted to allow the permitted modifications to occur as intended, subject to the safeguards in the permit.

In comparison to the opportunities for public involvement in the typical PSD permitting process, the Merck XL project offers the public an opportunity to be more fully informed about the environmental activities and changes at the facility. Absent Project XL, if Merck were to make a change at the facility that triggered a PSD permit review, the public would only have opportunity to comment on the specific project being permitted at that time. Further, it is difficult to speculate if and when the Merck Stonewall Plant would trigger a future PSD review, since it has never done so in its history. All of Merck's existing air permits are minor NSR permits. It is possible that Merck would have been required to undergo PSD review in the future (e.g., for a new pharmaceutical product line); however, the existing regulations would allow Merck to avoid PSD review if the emissions increase was less than the significance level, if it "netted out" of PSD review, or if it took a synthetic minor emissions limit. In any of these cases, the Commonwealth of Virginia would issue a minor NSR permit. Under the Commonwealth's minor NSR program, many types of permit changes can be made with little or no public participation. Even in cases where public participation is available under the minor NSR permitting process, public comment would be open only to the particular process being permitted. As explained above, for PSD permits as well as minor NSR permits, there is no term limit on the permit, and the public would not have an opportunity to comment on the facility's performance under the permit after the permit was issued.

Without this XL project, there would be no opportunity for stakeholders to participate in a regular five-year review

of the facility's operations, no opportunity for stakeholders to request permit changes to be considered, and no opportunity for the community to give consent to permit changes. By participating in the five-year permit review, the community will be much more fully informed about, and involved with, the facility's operations than they would under the traditional permitting system. During development of the initial XL project, all stakeholders learned a great deal of information about Merck's air emissions, emission units, monitoring methods, and facility operations. This level of information will continue to be shared during the stakeholder discussions for the five-year permit reviews. Under the traditional permitting process, the public would not have access to this level of facility-wide information, because the emissions information would be limited to the particular process undergoing permit review. Therefore, considering the full set of public participation opportunities under this XL project as compared to the traditional permitting system, EPA believes that Merck's XL project offers the public more comprehensive involvement in overseeing and reviewing facility operations.

In response to the comment regarding the term of permits in other XL projects, there is at least one other XL project in which a PSD permit is expected to be issued. In the Weyerhaeuser XL project, the State of Georgia plans to issue Weyerhaeuser a PSD permit as the mechanism to make enforceable the emissions caps described in the XL agreement. At this time, EPA understands that Weyerhaeuser's PSD permit will not have a limited duration. With regard to a commenter's concern about the permit term in the Merck XL project establishing precedent, EPA does not view any XL project as setting a precedent for future projects. Each project must be evaluated by the Agency and by stakeholders on an independent basis, considering the unique nature of the project and the company's full set of obligations under the proposed XL agreement.

3. Stakeholder and Public Involvement

a. *General.* Several citizens and environmental groups commented about the public participation involved in developing this proposed project. Merck commented that the stakeholders have made significant efforts to notify and educate the public about the project. A community meeting was held in December 1996, two public hearings were held in February 1997 and April 1997 (one by VADEQ and one by EPA),

a Merck retiree dinner was held, the Stonewall site's employees and Community Advisory Panel were briefed several times, several newspaper articles were published, and numerous newsletters and other documents were prepared and distributed to neighbors, retirees, employees, the media, and local state and federal government officials. In addition, Merck believes that the permit reviews represent a process that is unprecedented in air permitting in this country, and that the community will be provided with significant oversight of Merck's permit.

From Project XL's inception, EPA has stressed that stakeholder involvement and opportunities for public participation are critical to a project's success. During development of the Merck XL project, the public was given numerous opportunities for participation—far more than under the normal permitting process. Merck initiated a number of efforts to inform the local community about the project. EPA believes that Merck's comment provides a good summary of the communications outreach efforts undertaken during the development of this XL project. At the outset of the project, Merck developed and shared with the stakeholders a public involvement plan that included many of the activities described in Merck's comment above. This set of public involvement activities is fully consistent with the XL guidelines in place at the time of Merck's project development.

An environmental group commented that the stakeholder process for five-year permit review should follow EPA's April 23, 1997 XL guidelines in identifying and selecting direct participants and commenters. The commenter believes that "direct stakeholders" are those who sign off on the project and have a vote in the five-year review and potential permit changes. The commenter believes that the direct stakeholder group is not broad enough, because the commenter believes that EPA's XL guidance provides that additional stakeholders should be involved in the XL project development stage. Given that the Merck XL proposal has unlimited duration and a number of key issues were left to the five-year review process, the commenter recommends that the stakeholder process for periodic review should be equally as broad as the stakeholder process recommended by EPA for project development. The commenter requests EPA to ensure that the five-year review process meets the following [excerpt from 62 FR 19878–19879, April 23, 1997]: "The project sponsor should make special efforts to

recruit potential direct participants and commentors from among economically disadvantaged stakeholders and among stakeholders most directly affected by the environmental and health impacts of the project; * * * who have specific interest or expertise in the issues addressed in the project from among the national environmental justice communities and the industry segment of which the facility is a part; and * * * from among participating facilities' non-managerial employees." The commenter believes that the proposed make-up of the stakeholder group for permit review does not adequately reflect interest from these groups. In addition, a company located in Rockingham County, Virginia commented that it and other industries in the area should be considered significant stakeholders to the outcome and implementation of the project.

Merck commented that it sought to involve parties with a direct and specific stake in the project from the beginning. Merck maintained that a wide variety of interests was represented and all contributed to the innovative proposed permit. Based on the success of this process, Merck asserts that the proposed permit provides for these stakeholders to have a continuing opportunity for direct and valued input during operation under the permit as well. Merck believes that, particularly for the local community and regional public interest groups, these opportunities far exceed anything which they would be afforded under the current regulatory system. With regard to the April 23, 1997 XL notice's guidelines of three classes of stakeholders (general public, commentors, direct participants), Merck stated that it has considered its community representatives as "direct participants" since the project's inception, although it states that under this guidance they could have been considered "general public" with limited input. Merck points out that the XL guidance also states that the FPA should identify how to make information about the project, including performance data, available to stakeholders in an easily understandable form. Merck stated that it has committed to share with stakeholders and other interested parties an annual report. Merck further stated that it has committed to including all direct participant stakeholders in periodic evaluations, even though the guidelines indicate this would not be required. Merck believes that the permit's stakeholder process for five-year permit reviews is far beyond the level of stakeholder involvement

suggested in EPA guidance, and certainly beyond what is currently provided to the public in any other environmental permitting forum.

EPA agrees that the stakeholder group as defined in the Merck project meets the Agency's guidance regarding direct participant stakeholders. EPA believes that the stakeholder group, comprised of Merck, EPA, VADEQ, U.S. Department of the Interior, community representatives and a public interest group, represents a fair balance of interests. The excerpt from the April 23, 1997 XL notice submitted by one commenter pertains to the types of interests that should be represented by both direct participant stakeholders and "commenters". In the April 23, 1997 notice, "commenters" are described as those individuals or groups that have an interest in the project, but not the desire to participate as intensively in its development. EPA believes that the Merck project is consistent with the guidance by including direct participants in the makeup of the stakeholder group for five-year permit reviews. However, EPA does not agree that it is required that the stakeholder group must include "commenters" as described in the April 23, 1997 notice. EPA encourages the stakeholder group to establish a mechanism for communicating information about issues being discussed in the five-year reviews at appropriate points during the process, and to consider the input from "commenters", such as area industries or other environmental organizations.

A number of citizens and environmental groups commented that there should be more public involvement in the permit review process. A few citizens believe the proposed permit minimizes public participation in the permit review process, and that full public participation is supposed to be a major component of the XL program. Other citizens commented favorably about the opportunity for direct involvement of the local community in the oversight of the project.

A commenter maintained that the community representatives selected by the Rockingham County Board of Supervisors will not really have an effective voice in reviews and other decisions because their concerns can be vetoed by Merck or other signatories. A citizen commented that permit revisions should be decided by the majority, but not all of the project signatories, which might ensure that corrective adjustments to the permit are made. The commenter also suggested that a public hearing be held by VADEQ midway through each five-year review.

EPA disagrees that this project minimizes public participation in the permitting process. On the contrary, the permit provides for much greater public involvement than other permits of its type. This permit provides unique opportunities for public involvement through the stakeholder process and periodic permit reviews. In the PSD program, once a PSD permit is issued, normally there is no opportunity for future public involvement in the permit's implementation. The Merck PSD permit will provide a unique opportunity for strong public involvement in reviewing the facility's operations under the permit. Further, since there currently are no specific Federal regulations governing PSD permit revisions, typically EPA does not initiate PSD permit changes without consent of the permittee. PSD permit revisions usually are made at the request of the source, with consent of the source and the permitting authority. Accordingly, the EPA believes that providing an explicit veto for Merck, in conjunction with the extraordinary level of stakeholder involvement in the project, provides an appropriate level of assurance to Merck that the agreements on which this rule and permit are based upon will generally continue in their current form, subject to specific terms of the rule and permit, and to consensus-based permit changes.

Under Merck's PSD permit, Rockingham County and every other signatory will have an effective voice in the permit review process because changes to the permit generally must be made upon full consent of all the signatories. This means that there may be issues that Rockingham County, or any other one signatory, does not support and can thus "block" a change to the permit by not giving consent to the change. Rather than being viewed as a "veto", this process should be viewed as ensuring that a permit change is proposed only when there has been full discussion and consideration of the impacts of the change. Allowing permit changes to be decided by a majority of the signatories not only would erode Merck's ability to prevent changes that may be unworkable for its facility, but also would compromise the ability of any other signatory to prevent permit changes that it does not support. All stakeholders have an opportunity to be fully involved in these discussions and to raise issues, bring forth technical information, and offer proposed resolutions for consideration. This process is more likely to result in proposed permit changes that are the outcome of consensus among the

signatories. It is also important to note that Merck has no ability to "veto" any future enforcement actions or regulations which may impose additional requirements on the facility outside of the PSD permit.

The permit modification procedures in Merck's site-specific PSD rule (40 CFR 52.2454(n)) require the permitting authority to provide an opportunity for a public hearing for all permit modifications except those that meet the criteria for an administrative permit amendment (40 CFR 52.2454(n)(2)). Thus, if the signatories agree to any permit changes, the VADEQ must provide for public participation, including an opportunity for a public hearing, for those permit changes that do not qualify as administrative modifications. Any permit modification could also be appealed by residents or others with legal standing. EPA does not agree that it is necessary to provide for a public hearing during the five-year review process itself, since an opportunity for a public hearing will be provided if non-administrative permit modifications are proposed. EPA believes that public views can be effectively represented by the designated stakeholders during the process of developing any permit modifications. EPA encourages the stakeholder group to consider holding public meetings, similar to the one held during the initial project development, to inform the broader public of anticipated changes under consideration by signatories during the five-year review process. Other forms of communication (e.g., newsletters) to the public may be useful in communicating the issues under discussion and anticipated permit changes. EPA intends to continue to suggest effective forms of communication with the public during each five-year review and to participate in these activities along with the stakeholder group.

A citizen commented that the list of permit changes which the stakeholders can consider in the five-year reviews should be broadened to include, for example, permit termination, modification of caps, change in signatories, change in permit modification procedures, changes in significance levels, and others.

Section 6.1.1. lists the most fundamental types of permit changes anticipated by the stakeholders during the development of the project. In addition, these periodic review criteria will be reviewed by the stakeholders at each five-year review. EPA does not agree that it is necessary to add additional review criteria at this time, since it will be more effective to

consider new criteria, if necessary, at the time of each five-year review. The permit also provides that any stakeholder may raise issues about the PSD permit at any time, as needed.

b. *Project signatory consent to permit changes during five-year reviews.* In the notice of proposed rulemaking, EPA solicited comment on the approach to stakeholder involvement during the implementation of the Merck XL project. See 62 FR 15307 (March 31, 1997). EPA received a number of comments regarding the stakeholder process for reviewing the permit every five-years. Particularly, numerous comments were received on the issue of whether the consent of all stakeholders, or only the project signatories, should be required to make proposed permit changes (i.e., to recommend that the permitting authority process a permit modification). The permit generally requires consent of all project signatories prior to making a proposed permit change. Project signatories are defined as EPA, VADEQ, Merck, U.S. Department of the Interior Federal Land Manager, and the County of Rockingham. The permit also provides that additional stakeholders have an opportunity to directly participate in the permit review process, but their individual consent is not required for permit changes. These additional stakeholders include up to three community representatives and a regional public interest group. If the project signatories agree to permit changes, then the permitting authority may process a permit modification according to the requisite procedures (40 CFR 52.2454 (m) and (n)). These permit modification procedures require public participation, including a 30-day public comment period and opportunity for a public hearing, for any permit change not defined as an administrative modification.

EPA received a number of comments from citizens and environmental groups that the consent of the three community representatives, in addition to Rockingham County's consent, and the public interest group should also be required prior to making a permit change. Alternatively, Merck, citizens, industry representatives, and a state environmental agency supported the process established in the proposed permit, and that the County's consent is the appropriate representation of concerns of the community as a whole. The comments on this issue are summarized below.

One of the community representatives on the Merck XL stakeholder group supported that the three community representatives who are appointed to

the five-year periodic review should be allowed to come to consensus and then cast one single vote along with the signatories regarding proposed changes to the PSD permit. This commenter believes that the community at large should be directly involved in any permit changes, and that the interests of the County government and the local community at large are not necessarily the same and could differ vastly on proposed changes to the PSD permit. The commenter maintains that disallowing the three community representatives one single vote in this process reduces their input to a mere advisory role. This commenter believes that the local community at large looks to their community representatives and EPA for representation and protection. This community representative submitted a petition signed by about 240 people, which read "We the following residents of Rockingham County and Harrisonburg, do request with regard to the Merck XL Air Quality Project, Elkton, VA, that the three community representatives appointed to the project's five-year reviews be allowed to cast one vote along with the voting signatories to the project on proposed changes to the Prevention of Significant Deterioration (PSD) permit which replaces all other air quality permits."

An environmental group commented that the permit should provide for "stakeholder" consensus on permit changes, not just "signatory" consensus, because of the concern that the state, federal agencies, and Rockingham County could agree with Merck to raise the emissions cap, and the community representatives or public interest group would have no real say in that decision. The community and public interest group want to be assured that they are getting permanent reductions in emissions, and are concerned that the emissions caps could be increased in the future. This commenter believes that most of the permit was negotiated with the understanding that the community representatives, including, potentially, a regional public interest group, would have to agree to any permit changes. The commenter objects to the permit language being changed to provide community representatives and public interest group as "stakeholders" only. The commenter fully supports Rockingham County as a signatory, but believes the community representatives living downwind of the plant and the public interest group provide a perspective different from, and independent of, County concerns such as jobs and tax base.

A community representative on the Merck XL stakeholder group commented that there should be ground rules set up for the five-year reviews, and perhaps a neutral facilitator. This commenter and an environmental group also recommended that there should be funds set aside to provide technical assistance for the community at the five-year reviews, so that the community has a fuller understanding of the impacts of any permit changes under consideration.

A number of citizens and environmental groups commented that Merck should not have a "veto" over suggested permit changes. Some commenters expressed concern that, because full consent of the project signatories is needed for proposed permit changes, Merck can "veto" changes and ignore evidence of air quality and resource degradation in Shenandoah National Park. One commenter suggested that the stakeholder agencies should be responsible for determining the need for, and extent of, permit revisions. Absent that, the commenter believes that a funded, organized, strong public interest presence be included among the signatories.

EPA also received a number of comments supporting the roles of signatories and stakeholders in the five-year review process as proposed in the permit. Two citizens commented that they support having an elected member from the Rockingham County Board of Supervisors designated to represent the community. One of these commenters believes it is wrong for an individual citizen of the community to have a vote for approval of permit changes. The commenter states, "I could ask why I do not get the vote?" The commenter believes the elected officials will adequately represent him, and if not he has a recourse at the polls. With a community representative on the stakeholder group, he does not.

Several commenters, including a state environmental agency, industry association, a company that participated in another XL project, and Merck, commented that the local community interests, in particular, are afforded an unprecedented opportunity to participate in and influence the project. Many of these commenters expressed that the Merck XL project goes well beyond the role provided for community interests in the current regulatory system. These commenters strongly endorse having the community's voice on the stakeholder team through the local government, because it ensures representation of the interests of the whole community.

Merck commented that the permit's approach establishes an extremely important balance in community representation: it ensures that vocal and interested community members have a voice, and that the interests of the entire community are considered. Merck believes that it is appropriate that individuals who may be particularly concerned with the facility's operations, or who have specific expertise or input on a relevant issue, be provided with a full opportunity to voice their opinion. However, Merck maintains that meaningful community involvement must provide some assurance that the interests of the community as a whole are represented.

Two commenters maintained that it is an unusual suggestion that the Rockingham County Board of Supervisors does not represent the interests and well-being of County residents. These commenters assert that the local government is directly accountable to the residents that they represent; if the County officials fail to represent the community, the voters have a responsibility to remove those individuals and elect representatives that do. The commenters believe that a County appointee, in consultation with the three other community stakeholders, will be well equipped to voice the authentic views of the community. Merck believes that granting two community "votes" on the stakeholder group would not be providing a more open process, but rather, a more closed process that could allow the opinion of a few vocal individuals to prevail over the vital interests of the community at large.

Several commenters raised the concern that individuals representing only their own interests may adopt extreme positions which are not truly representative of community sentiment. Commenters stated that having a team of community representatives led by a local government official provides an appropriate measure of accountability and stability in the process.

Commenters believe that this approach will help assure that individuals who do not truly reflect the interests of the community as a whole are not granted a veto over a permit change that all other stakeholders otherwise find to be beneficial. Several commenters maintain that this system embodies the basic principles of our governmental system—accountable, elected representatives are charged with representing the peoples views on matters of public policy. A company that participated in Project XL contends that the function of community advisory groups must not be misinterpreted to

duplicate those of government. This commenter believes that stakeholder panels are an excellent means of getting early and meaningful input into environmental decisions, but, as both a practical and legal matter, they cannot assume the decisional role of government.

Merck and another company commented that the stakeholder process infuses a certain amount of risk for Merck, and that this additional risk is an important factor to consider when evaluating the adequacy of community involvement in future permit discussions. Merck stated that it could not accept a permit that would threaten the future viability of the plant. Merck believes that the permit was carefully crafted to ensure that it would provide enhanced community oversight, but not subject the plant to unacceptable control by outside parties. Merck commented that the proposed permit is crafted to reflect the process that was used in the formation of the project—each represented group is granted one “vote” in future permit reviews. Merck stated that none of the parties objected to this approach; all agreed that it was sensible that each party would reach a single position and bring that position to the stakeholder group. Merck believes it is unclear why this approach is now not acceptable.

Merck commented that the petition (referenced in a previous comment above) submitted to EPA does not provide any insights to what those who signed would be willing to accept as an alternative to two community votes, nor does it elucidate why they question their representation by Rockingham County and their ability to influence the County's views in future permit discussions. Merck believes that the County has already demonstrated the seriousness with which it accepts this charge to represent the community in the project negotiations. Merck stated that, despite an accelerated schedule to finish its review, in December 1996 the County insisted that it needed additional time for its independent technical consultant to analyze the draft permit and agreement before providing its consent. Merck believes that EPA should have every expectation that the County will continue to take its duty to represent community interests seriously.

Merck commented that a public interest group representative should not be added as a signatory. The permit specifies that a representative from a regional public interest group be included as a stakeholder, although not with the ability to vote on permit changes. Merck believes that this is a

unique opportunity for such groups which far exceeds that available to them under existing environmental regulations. Merck claimed that granting this representative with the same oversight as other signatories would be inappropriate and a serious compromise to the future viability of the Stonewall plant. Merck believes that a public interest group representative is not held accountable in any meaningful way to the public for his/her views. Merck maintains that the permit as crafted provides very significant input for public interest groups while assuring that only parties that have public accountability are granted oversight for permit changes.

Finally, Merck urged EPA to maintain the stakeholder provisions of the permit as proposed, because to include a second “vote” for the three community representatives would:

1. Endorse the accusation that the Rockingham County Board of Supervisors, despite being elected by the community, does not represent the community's interests.

2. Question the ability of EPA, DEQ, and NPS to act on legitimate environmental concerns for the protection of the public interest at large.

3. Indicate that the stakeholder process for the formation of the project is inadequate for project implementation.

4. Shatter the important balance that the County would bring as the lead representative of the entire community.

5. Contradict the XL guidance (April 23, 1997 **Federal Register** notice) by setting a standard for public involvement far above what could be required for future XL projects.

6. Agree that it is reasonable to have a process that would allow the opinion of a few vocal individuals to prevail over the interests of the community at large.

7. Narrow rather than broaden the representation of community interests on the project.

8. Suggest that the project stakeholders would not continue acting in good faith for future permit reviews.

9. Imply that Rockingham County's efforts to obtain independent review and advice on the agreement fell short of what is necessary to properly protect the community's interests; and

10. Threaten the future of a project that would otherwise provide the community with unprecedented oversight of Merck's air permit, that would significantly reduce actual emissions of pollutants of particular concern to the region, that would provide an ongoing incentive for the facility to minimize emissions, and that,

as EPA, VADEQ, National Park Service and the community have acknowledged, would provide superior environmental benefit.

In response, EPA believes that the permit represents a fair balance of interests. The permit significantly enhances the involvement of the community and other stakeholders in overseeing the environmental impacts of the Merck Stonewall Plant. 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 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, U.S. Department of the Interior 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 40 CFR 52.2454(n)). The permit identifies numerous issues that may be considered by the project stakeholders during each five-year review. Stakeholders also have the opportunity to raise issues of concern at any time for discussion by the stakeholder group.

The permit defines “project stakeholders” as the project signatories to the FPA 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 necessary. As discussed above, the 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 County of Rockingham 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 Manager 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.¹⁰ This model of stakeholder involvement provided all stakeholders with full information and ability to shape the development of the project.

EPA supports the provisions set forth in the proposed permit that require the consent of signatories only, and not the full stakeholder group, for proposed permit changes during the five-year review process. EPA agrees with several commenters that it is most appropriate that the representative of the Rockingham County Board of Supervisors will represent the views of the whole community, taking into account the interests and well-being of the County constituents. The role of the three community representative stakeholders also is important for identifying specific concerns, questions, and information that can influence the stakeholder discussions. EPA expects that Rockingham County's decisions about permit changes will substantially reflect the input and views of the three community representatives, as well as the interests of the community at large. Further, EPA believes that the five-year review process offers a role for a public interest group that is greatly enhanced as compared to the normal permitting process. The permit is designed such that all 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 does not believe that the permit's process for stakeholder involvement in any way diminishes the role of the non-governmental representatives. Throughout Project XL, EPA has made clear that it places a high degree of

importance on public support and will give the views of the public significant weight in deciding whether to proceed with a project. EPA will take the same approach on making decisions during project implementation. EPA will make every effort to ensure that the concerns of the community and the public interest group representatives are fully explored and addressed by the signatories. Prior to making a decision about whether to give consent to proposed permit changes, EPA intends to fully consider any outstanding concerns raised by the community representatives or the public interest group, and encourage other signatories to do the same.

This XL project is composed of an experimental, innovative emissions cap-based PSD rule and permit, which fully authorize modifications at the facility to occur without changes to the permit, so long as the emissions caps and other permit terms are met. Most future "modifications" thus will not require any permit changes and, therefore, will not need any agreement among the signatories; in these instances, any right of the stakeholders to vote on or veto changes will not be relevant. The signatory consensus process is relevant only for other types of changes at the facility necessitating changes to the permit. Regarding these latter kinds of permit changes (i.e., those not associated with a "modification") the EPA notes that the permit will continue to be governed by the site-specific rule (e.g., the caps must be consistent, or lower than, recent actual emissions, as discussed elsewhere in this document), and any resulting permit modification will occur only after stakeholder input during the five-year review process and will be judicially reviewable. As explained above, the EPA believes the level of stakeholder involvement in the Merck project is unprecedented in its scope and detail.

It is important to realize that any permit changes agreed to by the signatories must be processed by the permitting authority according to the required permit modification procedures. For the vast majority of changes (i.e., except those changes defined as administrative), the permitting authority is required to provide 30 days of public comment and an opportunity for public hearing. See 40 CFR 52.2454 (m) and (n). Thus, any member of the public will have a full opportunity to comment on any non-administrative changes agreed to by the signatories. It is the permitting authority's responsibility to fully evaluate and respond to any public comments received on proposed permit

changes. If the permitting authority determines that there is an inadequate basis for a proposed permit change, based on additional information received through public comments, the permitting authority may decide not to go forward with a particular permit change. This would be the permitting authority's decision to make, independent of the signatories. In this circumstance, the signatories could decide to reevaluate the proposed permit change and attempt to address the public comments and could request the permitting authority to re-propose the permit change. In addition, nothing in this rulemaking or the permit would limit a citizen's rights to judicial review of any final action taken by the permitting authority.

EPA believes that stakeholders, and other members of the public, are assured substantial rights in the event a permit modification is considered. Any significant modification would have to undergo public notice and comment, and would be subject to judicial review. Moreover, any decision to approve a modification would have to be supported by an administrative record, and stakeholders will have the opportunity, even prior to the formal notice and comment process, to submit information that might indicate that a modification was unwarranted. EPA has consistently made clear that in Project XL it is highly unlikely to take an action that does not have broad stakeholder support. In light of these protections, EPA does not believe it is necessary for the non-signatory stakeholders to have a formal veto. EPA believes that what is more important than vetoing changes proposed by others is the ability of the stakeholders and the public to propose changes when they believe the existing permit is not satisfactory. EPA believes the five-year review process will provide such an opportunity. Outside Project XL, no such opportunity would typically exist under a PSD permit.

Based on the public comments, EPA understands that one of the significant concerns of environmental groups and citizens is the possibility that the emissions caps will be raised in the future. The site-specific rule requires emissions caps to be established based on the site's actual emissions during a time period, within five years of permit issuance, which represents normal source operation, or a different time period if it is more representative of normal source operation. Reductions to the initial caps are required after the powerhouse conversion. Thus, the emissions caps generally could not be raised above these levels under this rule. The site-specific rule would need

¹⁰ 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).

to be revised in the future to authorize any increase in the emissions caps that is not already provided for in the rule or permit. For example, the permit provides that the emission caps may be increased in the following circumstances, which are primarily technical corrections: (1) The emissions caps may be adjusted to account for changes in emission factors which require a recalculation of the emissions baseline (i.e., to ensure an "apples to apples" comparison of current actual emissions to the emissions cap); and (2) the PM₁₀ emissions cap may be increased to account for the quantity of condensable PM₁₀ from the new powerhouse. These changes in emissions caps would not require a revision to the site-specific rule, since they are already authorized by the rule and proposed permit. However, if the signatories contemplate increases to the emissions caps for other reasons in the future, the site-specific rule would first have to be revised to authorize the cap increase. As part of the docket for such a rulemaking change, EPA would intend to ensure that an appropriate technical demonstration is conducted which justifies both the need for and the environmental impacts of the proposed emissions increases. EPA notes that any further decreases to the emissions caps (other than those already provided for in the permit) would require a revision of the permit, but not a revision of the site-specific rule.

EPA recognizes its responsibility to ensure meaningful participation in the stakeholder process, and will make every effort to accommodate the needs of stakeholders during the five-year permit reviews. EPA will make available its own technical expertise to respond to questions and concerns raised by the stakeholders. EPA also expects Merck to continue to provide assistance in understanding and evaluating technical issues. During the development of the Merck XL project, Merck made several technical presentations to the stakeholder group about various aspects of the project, including emissions calculation methodologies and how certain regulatory requirements affect the facility. Merck also hired a technical consultant to answer the stakeholders' questions about the impacts of potential VOC emissions on ozone formation. EPA expects that, as needed, Merck will continue to provide pertinent technical information to the stakeholders during the five-year review periods. Further, EPA hopes that Rockingham County will continue to seek technical advice and assistance during the five-year reviews, as it did during the initial

project development. Rockingham County employed a consultant from James Madison University to review the proposed XL project and make recommendations to the County. A County official commented that the consultant had a very good understanding of the process and the documentation provided. The County stated that the consultant recommended that the County support the project. The County's consultation with technical advisors can be a very effective way of addressing the technical assistance needs identified by the community.

EPA offered guidance on its ability to support technical assistance in a **Federal Register** Notice on Modifications to Project XL. See 62 FR 19872 (April 23, 1997). EPA recognizes that, in some cases, there will be a need for the Agency to offer some additional support for technical assistance to the "direct participant" stakeholder group.¹¹ The Agency has committed to provide up to \$25,000 per project over the next few years in order to assure that necessary technical assistance is available to support meaningful stakeholder involvement. As EPA explained in the April 23, 1997 **Federal Register** notice, EPA plans to make these funds available on a task-specific basis and funds will not be in the form of grants to stakeholder groups. EPA has issued a solicitation for proposals from not-for-profit and academic institutions to manage and operate a technical assistance program for Project XL stakeholders. The April 23, 1997 **Federal Register** notice explains additional qualifications on the use of this technical assistance. For example, technical assistance funds are not available to address strictly individual needs, but rather, needs for technical assistance must be identified and requested by the direct participant stakeholder group as a whole. For the Merck XL project, EPA fully intends to pursue making available similar resources at the time of the five-year periodic reviews to provide the technical assistance necessary to ensure a meaningful stakeholder process.

EPA agrees that the stakeholder process for five-year permit reviews could be enhanced by the use of a neutral facilitator and establishment of ground rules. However, EPA believes that these process decisions should be made by the entire stakeholder group at the outset of each five-year review. At the outset of the permit review process,

¹¹ In the April 23, 1997 **Federal Register** notice, "direct participants" are described as those stakeholder participants who work intensively with project sponsors during project development to build a project from the ground up.

EPA encourages the Merck XL stakeholder group to discuss the need for a neutral facilitator, and to establish a set of ground rules designed to guide the process and help ensure common expectations.

V. Administrative Requirements

A. Effective Date

Pursuant to 5 U.S.C. 553(d)(3) and 42 U.S.C. 6930(b)(3), EPA finds that good cause exists to make this rule effective immediately. The Merck & Co., Inc. Stonewall Plant is the only regulated entity affected by this rule. Merck has full notice of this site-specific rule, and is prepared to comply immediately with the permit to be issued expeditiously under the rule. Although EPA expects that the permit will not be issued for at least 30 days, an immediate effective date will allow the permitting process to proceed without delay.

B. Executive Order 12866

Because this rule only affects one facility, it is not a rule of general applicability and therefore not subject to OMB review under Executive Order 12866. In addition, OMB has agreed that reviews of site-specific rules under Project XL are not necessary.

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), P.L. 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 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.

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: September 30, 1997.

Carol M. Browner,
Administrator.

For the reasons set forth in the preamble of this rule, parts 52, 60, 264 and 265 of chapter I of title 40 of the Code of Federal Regulations are 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.

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, VA.

(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 (PM₁₀), and sulfur dioxide. This section applies in lieu of § 52.21 for the pollutants identified in this paragraph as well as particulate matter, but not for particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 microns (PM_{2.5}) regulated as PM_{2.5}; 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 shutdown 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 PM₁₀.

(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 PM₁₀ 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 PM₁₀.

(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 PM₁₀.

(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 section 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) of this section;

(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 parts 210 and 211) in force at the site.

(1) *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: the Administrator, 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 §§ 60.40b through 60.49b(t) 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 paragraphs (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 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.

Subpart BB—[Amended]

3. Section 264.1050 is amended by adding paragraph (g) 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.

Subpart CC—[Amended]

4. Section 264.1080 is amended by adding paragraph (e) 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.

Subpart AA—[Amended]

2. Section 265.1030 is amended by adding paragraph (c) 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.

Subpart BB—[Amended]

3. Section 265.1050 is amended by adding paragraph (f) 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.

Subpart CC—[Amended]

4. Section 265.1080 is amended by adding paragraph (e) 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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