January 7, 1998

Mr. Donald T. Kremer
Plant Manager
Merck & Co., Inc.
P.O. Box 7
Elkton, Virginia 22827-0007

Location: Rockingham County
Registration No.: 20524
County-Plant No.: 165-0001

Dear Mr. Kremer:

Attached is a permit to modify and operate the Merck Stonewall Plant in accordance with the provisions of the Commonwealth of Virginia State Air Pollution Control Board (SAPCB) Regulations for the Control and Abatement of Air Pollution, including 9 VAC 5-190-10 et seq. (Variance for Merck Stonewall Plant) and the SAPCB Order dated September 11, 1997.

The permit contains legally enforceable conditions. Failure to comply may result in a Notice of Violation and civil penalty.

In the course of evaluating the permit request, and arriving at a final decision to approve the project, the Department of Environmental Quality deemed the application complete on December 27, 1996, and solicited written public comments by placing a newspaper advertisement in the January 28, 1997 Daily News-Record. The thirty-day public comment period (provided for in 9 VAC 5-80-10.G.4) was extended until May 31, 1997, to run concurrent with EPA s public participation period on the project.

This approval to modify and operate shall not relieve Merck & Co., Inc. of the responsibility to comply with all other applicable local, state and federal permit regulations.

Please be advised that you may petition the Environmental Appeals Board pursuant to 40 CFR 124.19 (Code of Federal Regulations) to review any condition of the final PSD decision. You have 30 days from the date you actually received this permit or the date it was mailed to you, whichever occurred first, within which to initiate an appeal. In the event that you receive this permit by mail, three days are added to

the period in which to file an appeal. The address to send your appeal is:

Environmental Appeals Board
U.S. Environmental Protection Agency
401 M Street, SW (1103B)
Washington, DC 20460

9 VAC 5-170-200 of the Board s Regulations provides that you may also request a formal hearing from this case decision by filing a petition with the Board within 30 days after this case decision

notice was mailed or delivered to you. Please consult the relevant regulations for additional requirements for such requests.

Additionally, as provided by Rule 2A:2 of the Supreme Court of Virginia, you have 30 days from the date you actually received this permit or the date on which it was mailed to you, whichever occurred first, within which to initiate an appeal to court by filing a Notice of Appeal with:

Thomas L. Hopkins, Director
Department of Environmental Quality
P.O. Box 10009
Richmond, Virginia 23234-0009

In the event that you receive this permit by mail, three days are added to the period in which to file an appeal. Please refer to Part Two A of the Rules of the Supreme Court of Virginia for additional information, including filing dates and the required content of the Notice of Appeal.

If you have any questions concerning this permit, please contact Mike Kiss at (540)574-7822.

Sincerely,

R. Bradley Chewning, P.E.

Attachments: Permit
40 CFR 124.19

cc: Director, Office of Permit Support (electronic file submission)
Director, Office of Data Analysis (electronic file submission)
Director, Office of Compliance and Enforcement (electronic file submission)
Chief, Air Enforcement Branch (3AT20), U.S. EPA, Region III
Superintendent, Shenandoah National Park
Project XL Stakeholders

PREVENTION OF SIGNIFICANT DETERIORATION PERMIT

STATIONARY SOURCE PERMIT TO MODIFY AND OPERATE

In compliance with the Federal Clean Air Act and the Commonwealth of Virginia Regulations for the Control and Abatement of Air Pollution,

Merck & Co., Inc.
P.O. Box 7
Elkton, Virginia 22827-0007
Registration No. 20524
County-Plant No. 165-0001

is authorized to modify and operate the

Merck Stonewall Plant

located

4 miles south of Elkton on Virginia Route 340
Rockingham County, Virginia

in accordance with the Conditions of this permit.

approved on _____ , with an effective date of

_____ , pending petition of this decision.

_____
Director, Department of Environmental Quality

Permit consists of 36 pages.

1. Site-wide Emissions Caps

1.1. Initial Site-wide Emissions Caps

1.1.1. Total Criteria Pollutant Emissions Cap: The total criteria pollutant emissions cap (total emissions cap) is 1503 tons per year (TPY). The criteria pollutants included in the cap are the following: ozone (using volatile organic compounds (VOCs) as surrogate), sulfur dioxide (SO_2), particulate matter with aerodynamic diameter less than 10 microns (PM-10), carbon monoxide (CO), and oxides of nitrogen (NO_x).

1.1.2. SO_2 cap: The SO_2 cap is 719 TPY.

1.1.3. PM-10 cap: The PM-10 cap is 42 TPY.

1.1.4. NO_x cap: The NO_x cap is 291 TPY.

1.2. Adjustments to the Site-wide Emissions Caps

The site-wide emissions caps shall be adjusted as follows:

1.2.1. Initial benefit to the environment

a. Upon completion of the powerhouse conversion, the total emissions cap shall be reduced to 1202 TPY, a 20% reduction of the total from Subsection 1.1.

b. Upon completion of the powerhouse conversion, the SO_2 cap shall be reduced to 539 TPY, a 25% reduction of the total from Subsection 1.1.

c. Upon completion of the powerhouse conversion, the PM-10 cap shall be 42 TPY.

d. Upon completion of the powerhouse conversion, the NOx cap shall be reduced to 262 TPY, a 10% reduction of the total from Subsection 1.1.

1.2.2. Adjustments for criteria pollutant regulations

Prior to the compliance date of a criteria pollutant regulation[1], including New Source Performance Standards (40 CFR 60 and VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 5 (9 VAC 5-50-400 et seq.)), to which the site or a source at the site is newly subject, Merck will either plan to implement the regulation as written by the compliance date, or adjust the site-wide emissions caps as follows:

a. Merck shall determine the reduction in total actual emissions that would result from complying with the regulation on the compliance date. The total reduction will be based on the site s operations and production rate corresponding to the time period defined by the highest emission point (HEP) or another more appropriate emission rate, as agreed upon by the regulatory administering agency and Merck.

b. Proposed adjustment of site-wide emission caps: site-wide emission caps will be proposed to be adjusted as follows:

i. The SO_2 cap reduced by the reduction in total actual emissions of SO_2 that would result from complying with the new regulation

ii. The PM-10 cap reduced by the reduction in total actual emissions of PM-10 that would result from complying with the new

[1] A regulation promulgated under the Clean Air Act Title I or Virginia Air Pollution Control Law covering only those pollutants listed in Section 1.1 of this permit.

regulation

iii. The NO_x cap reduced by the reduction in total actual emissions of NO_x that would result from complying with the new regulation

iv. The total emissions cap reduced by the reduction in total actual emissions of CO or VOCs, as appropriate, that would result from complying with the new regulation

c. Approval of cap adjustment:

i. Merck will submit the emission reduction determination and rationale to the regulatory administering agency for review and approval on a date prior to the compliance date of the regulation which is no later than 120 days for new regulations, or no later than 90 days for existing regulations to which the site or a source at the site is newly subject. Merck shall provide additional documentation of the reduction estimate in a timely manner if requested. If Merck fails to comply with the requirements of this paragraph, Merck shall comply with the regulation as written.

ii. The emission reduction determination will be considered approved by the administering agency unless Merck is notified in writing within 60 days of the initial notification provided in (i).

iii. If the regulation is administered by EPA under a Federal Implementation Plan (CAA Section 110) or if it is an NSPS other than Subpart Kb[2] (40 CFR 60.110b et seq.), Merck shall implement the regulation as written by the compliance date if: (1) EPA determines that compliance with the regulation instead of a cap adjustment is necessary for achieving the objectives of the regulation, and (2) EPA notifies Merck in writing within 60 days of the initial notification provided in (i).

iv. Except as provided in paragraph 1.2.2(c)(iii), if it does not agree with Merck s estimate provided in (c)(i), the administering agency shall provide an alternate reduction estimate based on the site s operations and production rate as described in (a) and accepted emission estimation methods described in Table 4.3.

v. Except as provided in paragraph 1.2.2(c)(iii), the parties will seek agreement on the reduction estimate that represents the reduction that would be effected by the regulation. Until an agreement is reached, the site shall operate with the site-wide emissions caps reduced by the amount determined by Merck in (a) and (b), and shall be deemed to be in compliance with the regulation.

vi. Except as provided in paragraphs 1.2.2(c)(iii) and (v), if the parties have not obtained agreement on the appropriate reduction estimate within three months of the administering agency s response in (c)(ii), Merck shall have the option of either: adjusting the site-wide emissions caps by amounts determined by the administering agency in (c)(iv), or complying with the

[2] If the regulation is NSPS Subpart Kb including associated provisions of Subpart A, subparagraph (iii) would not apply.

regulation as written no later than a date agreed upon by the parties which shall be no later than 12 months after the compliance date of the regulation.

d. The site-wide emissions caps will be reduced as described in (b).
e. The adjustments to the site-wide emissions caps will represent compliance with the regulation.

1.2.3. Adjustments for Hazardous Air Pollutant (HAP) Regulations
No adjustment of the emissions caps shall be required when complying with applicable HAP regulations.[3]

1.3. Operating under the Emissions Caps

1.3.1.

a. The site s actual emissions of criteria pollutants shall not exceed the total emissions cap established in subsections 1.1 and 1.2.
b. The site s actual emissions of SO_2, PM-10, and NO_x shall not exceed the individual pollutant caps established in subsections 1.1 and 1.2.
c. Compliance with the total emissions cap and individual pollutant caps shall be determined by comparing the specific 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. Merck shall use the calculation techniques identified in Table 4.3 to calculate site-wide actual criteria pollutant emissions.

1.3.2. Installation of controls for significant modifications and significant new installations

a. Subsection 1.3.2 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 Subsection 1.3.2 (b). 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 Subsection 1.3.2 (b). 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.
b. Significance levels for determining significant modifications and significant new installations :

40 TPY VOC
100 TPY CO
40 TPY NO_x
40 TPY SO_2
15 TPY PM-10

c. For any significant modification or significant new installation Merck shall install at the process unit emission controls, pollution prevention or other technology that represents good environmental engineering practice in the pharmaceutical or batch processing

[3] A state or federal regulation promulgated under the Clean Air Act Title III.

industry, based on the emission characteristics (flow, variability, pollutant properties, etc.) of the process unit. Examples of emission controls that meet this requirement include, but are not limited to:

- condensation for high concentration VOC streams
- thermal oxidation for low concentration high flow VOC streams
- carbon adsorption for low concentration low flow VOC streams
- water or caustic scrubbing for acid gases and water soluble compounds
- water or acid scrubbing for caustic gases
- dust collection (bag filters) or other particle removal for particulates
- low NO_x technology for significant NO_x combustion sources

1.3.3. Operation of listed control equipment

Merck shall continue to operate the emissions control equipment listed in Table 1.3.3 as follows: the 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.

1.3.4. Prohibition on emissions trading

Emission reductions of criteria pollutants listed in Sections 1.1 and 1.2 shall not be credited for trade or sale to any other site. Nor shall Merck increase its allowable emissions through acquisition of emissions credits from the open market or from any other site.

1.3.5. Prohibition for acid rain opt-in program

Merck shall not participate in the acid rain program under the opt-in provisions of Clean Air Act Section 410.

1.3.6. Control requirements for certain units

a. Units that would otherwise be subject to requirements in 40 CFR 264 Subpart AA (40 CFR 264.1030 et seq.), or 40 CFR 265 Subpart AA (40 CFR 265.1030 et seq.), shall be controlled with a secondary brine condenser or thermal oxidizer, and monitored as specified in Section 4.

b. Merck shall continue its maintenance and repair program (that resulted in the site-specific emission factors referenced in Table 4.3) for all equipment components (valves, flanges, pumps, compressors, sampling connections) that are in contact with VOCs and/or volatile organics (volatile organics as defined in 40 CFR 264 and 265).

c. Merck shall install and maintain covers with no visible holes, gaps, or other open spaces on all containers that would otherwise be regulated under 40 CFR 264 Subpart CC (40 CFR 264.1080 et seq.), or 40 CFR 265 Subpart CC (40 CFR 265.1080 et seq.).

d. Merck shall install covers with no visible holes, gaps, or other open spaces on all storage/accumulation tanks that would otherwise be subject to the tank provisions of 40 CFR 264 Subpart CC (40 CFR 264.1080 et seq.), or 40 CFR 265 Subpart CC (40 CFR 265.1080 et seq.). Fixed-roof tanks may be equipped with one or more

conservation vents.

e. Merck shall install covers with no visible holes, gaps, or other open spaces on hazardous waste treatment tanks that would otherwise be subject to the treatment tank provisions of 40 CFR 264 Subpart CC (40 CFR 264.1080 et seq.), or 40 CFR 265 Subpart CC (40 CFR 265.1080 et seq.). Such tanks shall either be equipped with a floating roof, or be vented to a brine condenser or thermal oxidizer and monitored as specified in Section 4.

2. Powerhouse Conversion

2.1. Commitment to Convert Powerhouse

Merck shall convert the site s steam-generating powerhouse from burning coal as the primary fuel to natural gas as primary fuel and either #2 fuel oil or propane as backup fuel. The new boilers shall be equipped with low NO_x technology.

2.2. Timeframe for conversion

The conversion shall take place according to the following schedule:

2.2.1. Merck expects to contract with a boiler manufacturer for two natural gas-fired boilers within six months of the effective date of the PSD permit. A contract for purchase of two natural gas-fired boilers shall be made no later than 12 months after the effective date of the PSD permit.

2.2.2. Merck expects to complete the powerhouse conversion 18 months after the effective date of the PSD permit. Completion of the powerhouse conversion shall take place no later than 30 months after the effective date of the PSD permit.

2.3. Merck shall provide the following information to the project signatories:

2.3.1. Notification within 30 days after commencement of powerhouse conversion

2.3.2. Notification within 30 days after completion of powerhouse conversion.

2.3.3. Notification that stack test of the powerhouse has been performed, and an estimate based on that stack test of the actual emission reductions achieved from the conversion.

2.4. Regulatory Compliance for the Powerhouse

2.4.1. This PSD permit is deemed to be the preconstruction permit for the powerhouse conversion project described in this section for purposes of Major New Source Review Permitting and Minor New Source Review Permitting (40 CFR 52.21 and VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 4 (9 VAC 5-50-240 et seq.), 9 VAC 5-80-10, 9 VAC 5-80-11, 9 VAC 5 Chapter 80, Part II, Article 8 (9 VAC 5-80-1700 et seq.), and 9 VAC 5-20-160).

2.4.2. Compliance with this permit shall be deemed to be compliance with all requirements of 40 CFR 60 Subpart Db (40 CFR 60.40b et seq.) and 9 VAC 5 Chapter 50, Part II, Article 5 (9 VAC 5-50-400 et seq.).

3. Compliance with State and Federal Regulations and Air Permits Under the PSD permit. This permit allows Merck to construct or modify emission units at the site. Any such permitted activities would not be subject to any further PSD, NSR or minor NSR preconstruction permitting requirements for the pollutants as specified in Sections 3.2 and 3.3.

3.1. This permit replaces all other pre-construction permits issued to the site prior to the effective date of this section, including:

Sludge Dryer, Permit Date 12/16/97
MK-991 Process, Permit Date 11/24/97
CRIXIVAN® Process, Permit Date 11/19/97
Lovastatin Process, Permit Date 8/20/97
Fire Pump Diesel Generator Permit Date 2/28/96
Powerhouse Diesel Generator, Permit Date 9/9/94
Sterile Bulk Pharmaceutical Facility Centrifuge (Cefoxitin), Permit Date 9/3/93
Pharmaceutical Film Tablet Coating Pan, Permit Date 7/31/92
Efrotomycin Process, Permit Date 6/7/88
Primaxin Manufacturing, Permit Date 8/25/83
Powerhouse, Permit Date 1/28/82
Waste Disposal Incinerator, Permit Date 8/12/81
Cefoxitin Process, Permit Date 10/27/76
Activated Sludge Incinerator, Permit Date 5/28/76
MPMD Pharmaceutical Tablet Manufacturing, Permit Date 6/16/75

3.2. Major New Source Review (NSR) Permitting and Registration
Compliance with this permit shall be deemed to satisfy all requirements of the major NSR permitting and registration regulations (40 CFR 52.21, 40 CFR 52.2420 as it pertains to major NSR permitting and registration, and VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 4 (9 VAC 5-50-240 et seq.), 9 VAC 5 Chapter 80, Part II, Article 8 (9 VAC 5-80-1700 et seq.), 9 VAC 5-80-30, and 9 VAC 5-20-160) for pollutants listed in Section 1.1 and particulate matter (PM), but not for particulate matter regulated as PM-2.5.

3.3. Other Regulations for Which the PSD permit Constitutes Compliance
Compliance with this permit shall be deemed to satisfy all requirements of the following regulations for all pollutants except Lead, except particulate matter regulated as PM-2.5, and except any new criteria pollutants listed by EPA in 40 CFR 52.21(b)(23)(i) after issuance of this permit:

3.3.1. Minor NSR Permitting and Registration
40 CFR 52.2420 as it pertains to minor NSR permitting and registration, and VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 4 (9 VAC 5-50-240 et seq.), 9 VAC 5-80-10, 9 VAC 5-80-11, and 9 VAC 5-20-160

3.3.2. Standards of Performance for Stationary Sources
VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 4 (9 VAC 5-50-240 et seq.) , and 40 CFR 52.2420, as it pertains to 9 VAC 5-50-240 et seq., standards of performance for stationary sources

3.3.3. Virginia Air Toxics Rule
VA Air Regulations 9 VAC 5 Chapter 40, Part II, Article 3 (9 VAC 5-40-160 et seq.) and 9 VAC 5 Chapter 50, Part II, Article 3 (9 VAC 5-50-160 et seq.)

3.3.4. Notification, Records, and Reporting
VA Air Regulations 9 VAC 5-40-50 and 9 VAC 5-50-50, and 40 CFR 52.2420 as it pertains to 9 VAC 5-40-50 and 9 VAC 5-50-50, notification, records and reporting.

3.3.5. Emission Standards for General Process Operations, Incinerators, and Fuel Burning Equipment
VA Air Regulations 9 VAC 5 Chapter 40, Part II, Article 4 (9 VAC 5-40-240 et seq.) , 9 VAC 5 Chapter 40, Part II, Article 7 (9 VAC 5-40-730 et seq.), and 9 VAC 5 Chapter 40, Part II, Article 8 (9 VAC 5-40-880 et seq.), and 40 CFR 52.2420 as it pertains to VA Air Regulations 9 VAC 5 Chapter 40, Part II, Article 4, 9 VAC 5 Chapter 40, Part II, Article 7, and 9 VAC 5 Chapter 40, Part II, Article 8, Emission Standards for General Process Operations, Incinerators, and Fuel Burning Equipment

3.3.6. Compliance and Monitoring
VA Air Regulations 9 VAC 5-40-20, 9 VAC 5-40-21, 9 VAC 5-40-22, 9 VAC 5-40-40, 9 VAC 5-40-41 and 9 VAC 5-50-40, and 40 CFR 52.2420, as it pertains to 9 VAC 5-40-20, 9 VAC 5-40-21, 9 VAC 5-40-22, 9 VAC 5-40-40, 9 VAC 5-40-41 and 9 VAC 5-50-40, compliance and monitoring

3.3.7. RCRA Organic Air Emissions Standards
40 CFR 264 Subparts AA and BB (40 CFR 264.1030 et seq. and 264.1050 et seq.), and 40 CFR 265 Subparts AA and BB (40 CFR 265.1030 et seq. and 265.1050 et seq.)

3.4. Regulations for Which This Permit Constitutes Compliance for Certain Provisions

Compliance with this permit shall be deemed to satisfy certain requirements of the following regulations for all pollutants, except Lead, except particulate matter regulated as PM-2.5, and except any new criteria pollutants listed by EPA in 40 CFR 52.21(b)(23)(i) after issuance of this permit. Merck shall continue to comply with other sections of these rules as specified in the regulations. These regulations and the portions for which the PSD permit constitutes compliance are specified below.

3.4.1. Standards of Performance for New Stationary Sources (NSPS)
The PSD permit constitutes compliance with 40 CFR 60 Subpart Kb (40 CFR 60.110b et seq.), 40 CFR 60 Subpart A (40 CFR 60.1 et seq.), VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 5 (9 VAC 5-50-400 et seq.), and 40 CFR 52.2420 as it pertains to VA Air Regulations 9 VAC 5 Chapter 50, Part II, Article 5, for new and existing bulk volatile organic liquid storage vessels (including petroleum liquid storage vessels) that would otherwise only be subject to notification, recordkeeping and reporting requirements.

3.4.2. Title V Permitting

a. Monitoring Requirements: Monitoring requirements specified in Section 4 of the PSD permit shall constitute compliance with any applicable monitoring requirements in 40 CFR 71.6(a)(3) and 9 VAC 5-80-110 E that would be applicable to provisions of this permit.

b. Recordkeeping and Reporting Requirements: Recordkeeping and reporting requirements specified in Section 4 of the PSD permit shall constitute compliance with recordkeeping and reporting requirements that would be applicable to provisions of the PSD permit in 40 CFR 71.6(a)(3)(ii), 40 CFR 71.6(a)(3)(iii)(A), 9 VAC 5-80-110.F.1, and 9 VAC 5-80-110.F.2.a

3.4.3. CERCLA and EPCRA Emergency Release Reporting (40 CFR 302, 40 CFR 355.40)
Emissions in compliance with this permit are federally permitted releases for purposes of release reporting under Section 103(a) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and Section 304 of the Emergency Planning and Community Right-To-Know Act (EPCRA).

3.4.4. Facility and control equipment maintenance or malfunction compliance
VA Air Regulations 9 VAC 5-20-180 and 9 VAC 5-50-20, and 40 CFR 52.2420 as it pertains to 9 VAC 5-20-180 and 9 VAC 5-50-20, facility and control equipment maintenance or malfunction compliance (except for visible emissions and odor).

3.4.5. Control Programs
VA Air Regulations 9 VAC 5-20-170, and 40 CFR 52.2420 as it pertains to 9 VAC 5-20-170, Control Programs (except for visible emissions and odor).

3.4.6. Compliance, Monitoring and Performance Testing
VA Air Regulations 9 VAC 5-40-30, 9 VAC 5-50-30, and 40 CFR 52.2420 as it pertains to 9 VAC 5-40-30 and 9 VAC 5-50-30, Compliance, Monitoring and Performance Testing (all except 9 VAC 5-40-30B and 9 VAC 5-50-30B, which subject emission testing to approved guidelines)

3.4.7. RCRA Organic Air Emissions Standards for Tanks and Containers
40 CFR 264 Subpart CC (40 CFR 264.1080 et seq.), and 40 CFR 265 Subpart CC (40 CFR 265.1080 et seq.), except for provisions applicable to surface impoundments.

3.5. Compliance with the terms of this permit shall not relieve Merck of its obligation to comply with applicable local, State or Federal laws and regulations not addressed in this section.

3.6. Violation of a term of this permit shall not constitute a violation of regulations listed in this section for which the permit constitutes compliance.

4. Monitoring, Recordkeeping and Reporting
Merck shall comply with the monitoring, recordkeeping and reporting requirements specified in Table 4.2. Monitoring, recordkeeping and reporting as prescribed in this section shall constitute the basis for Merck s certification of compliance with the provisions of this PSD permit pursuant to Title V.

4.1. Reporting Tiers:

4.1.1. Tier I requirements are in effect whenever the actual criteria pollutant emissions for the last 12 months are determined to be greater than 0% and less than 75% of the total emission cap, and during the startup period of the permit (the period between the effective date of this section and 12 months after completion of the powerhouse conversion project).

4.1.2. Except as provided in 4.1.1, Tier II requirements are in effect whenever the actual criteria pollutant emissions for the last 12 months are determined to be equal to or greater than 75% and less than 90% of the total emission cap.

4.1.3. Except as provided in 4.1.1, Tier III requirements are in effect whenever the actual criteria pollutant emissions for the last 12 months are

determined to be equal to or greater than 90% of the total emission cap.

4.2. Except as provided in 4.11, Tier I, II and III monitoring, recordkeeping and reporting requirements for SO_2, PM-10, NO_x, CO and VOCs are found in Table 4.2.

4.3. Emission Calculation Techniques

4.3.1. Table 4.3 specifies the emission calculation techniques to be used for each emission type at the site.

4.3.2. Adjustment to the PM-10 Emission Cap: Upon completion of the powerhouse stack test required in Table 4.2, the PM-10 emission cap shall be adjusted as follows:

a. Merck shall submit the stack test results to VADEQ for confirmation that the test was performed correctly.

b. The powerhouse s condensable PM-10 emission rate shall be determined as: the sum of (1) the quantity of condensable PM-10 measured while burning natural gas at full load (in lb/day) times 345 days, and (2) the quantity of condensable PM-10 estimated while burning backup fuel at full load (in lb/day) times 20 days, converted to TPY.

c. The PM-10 emission cap in 1.2.1(c) shall be increased by the powerhouse s condensable PM-10 emission rate as determined in (b) or 10 TPY, whichever is less. Operation of this provision shall trigger an administrative permit modification only.

4.3.3. If the AP-42 emission factors described in Table 4.3 are updated, and the project signatories fail to agree upon appropriate changes needed to incorporate these updated factors into the permit as provided in Section 6.1.1, VADEQ may at its discretion initiate the following actions:

a. Describe to the project stakeholders in writing that use of the updated AP-42 emission factor is important for the technical validity of the site s emission calculations.

b. Obtain from Merck: 1) confirmation that the emission source(s) at the site are the same type of sources as those for which the AP-42 emission factor applies, and (2) agreement on how the emissions caps, HEP and current actual emissions should be adjusted to reflect the updated emission factor.

c. Provided that agreement is reached in (b), initiate the permit modification procedure to incorporate the change into the permit.

4.4. Monthly Requirements:

4.4.1. Beginning on the first day of each month, Merck shall perform the monitoring, recordkeeping and reporting requirements in Table 4.2 according to the reporting tier determined by the 12-month rolling total of criteria pollutant emissions of the period ending two calendar months prior to that date. The monthly calculations specified in Table 4.2 shall cover the period which ended one calendar month prior to that date.

4.4.2. Example

a. By 2/1/97 calculate the 12-month rolling total of criteria pollutant emissions for 1/1/96 through 12/31/96.

b. Assume 1/1/96-12/31/96 emissions total equals 80% of total emissions cap.

c. Assume Tier I requirements were in effect 1/97 and prior.

d. For the month of March 1997, Tier II monitoring, recordkeeping and reporting requirements would be in effect.
e. Twelve-month rolling total including the first month of Tier II data (from 3/97) will be calculated by 5/1/97 for period 4/1/96 through 3/31/97.

4.5. Annual and Semi-Annual Requirements:
4.5.1. On September 1 of each year, Merck shall submit a semi-annual report for the six-month period ending June 30th if any tier reached during that period required a semi-annual report.
4.5.2. On March 1 of each year, Merck shall submit a semi-annual report for the six-month period ending December 31st if any tier reached during that period required a semi-annual report.
4.5.3. On March 1 of each year, Merck shall submit an annual report for the 12-month period ending December 31st.

4.6. Reports required in this section shall be submitted to the project signatories.

4.7. Reports specified in Section 4.5 shall contain 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.

4.8. Records required in this section shall be retained on site for at least five years.

4.9. Annual Progress Report
In addition to the reports otherwise required in the section, Merck shall submit to the project stakeholders and to other parties an annual progress report. This report shall include a summary of the site s actual emissions and site-wide emission caps, emissions prevented as a result of the PSD permit, and other information about the site and the operation of the PSD permit.

4.10. Adherence to Continuous Monitoring Requirements
This paragraph applies to each of the monitoring systems required by this permit. Adherence to the requirement to monitor continuously shall be demonstrated by either 4.10.1 or 4.10.2.
4.10.1. Collection of at least 90% of the data required to be collected by the permit during any one month, or
4.10.2. Collection of less than 90% of the data required to be collected by the permit during any one month, and either
a. verification and documentation through independent means sufficient to establish that the control device was operating properly during the period that the monitoring system failed to collect data, or
b. the assumption for the purpose of emission calculations that the control device was not operating during the period that the monitoring system failed to collect data.

4.11. HAP Monitoring and Emission Testing Requirements Under CAA Section 112(d)
4.11.1. Compliance with monitoring requirements required for a particular control device under an applicable CAA 112(d) regulation shall constitute compliance with any Section 4 monitoring requirement applicable to that device.
4.11.2. Compliance with emission testing requirements required for a particular control device under an applicable CAA 112(d) regulation shall constitute compliance with any Section 4 emission testing requirement

applicable to that device.

4.12. In addition to the requirements in Section 3.4.4 for visible emissions and odor, the VADEQ shall be notified of each event involving malfunction or bypass of a control device listed in Table 1.3.3 or any new control device installed pursuant to Section 1.3.2, if the total criteria pollutant emissions resulting from such event are expected to exceed 5% of the total emissions cap. This notification shall be provided no later than four (4) daytime business hours after the determination of applicability of this section is made.

5. Phase In of PSD Permit Terms

5.1. All sections of the PSD permit are effective upon the effective date of this permit except:

5.1.1. Section 1: Site-wide Emissions Caps

5.1.2. Section 3: Compliance with State and Federal Regulations and Air Permits Under the PSD Permit

5.1.3. Section 4: Monitoring, Recordkeeping and Reporting

5.2. Sections 1, 3 and 4 of the PSD permit are effective on the first day of the month 12 months after completion of the powerhouse conversion project or after written notification is provided by Merck to the project stakeholders, whichever is sooner.

5.3. If Sections 1, 3, and 4 of this permit become effective prior to 12 months after completion of the powerhouse conversion project pursuant to Section 5.2, Merck shall conduct a performance test on any control device installed pursuant to Section 1.3.2, excluding condensers and conservation vents. Such performance test shall be conducted within 180 days of the start-up of the unit. This condition shall cease to be applicable once Section 1.2.1 becomes effective.

6. Periodic Review of the PSD Permit

The PSD permit shall be periodically reviewed as specified in this section. Changes to the PSD permit shall be made either: after full consent of the project signatories and subject to the permit modification procedures promulgated in Merck s site-specific rule, or pursuant to PSD permit modification procedures generally applicable to all PSD permits. Changes to the PSD permit other than those described below are not subject to review except as otherwise agreed to by full consent of the project signatories. Discussion of issues brought by the project stakeholders relating to the PSD permit may occur as needed.

6.1. Five-Year Periodic Review

Within three months of the five year anniversary of the completion of the powerhouse conversion project and every five years thereafter, the project stakeholders shall reconvene to review whether any of the following changes to the PSD permit are required.

6.1.1. Significant changes in calculation methods – Current state-of-the-art emission estimation techniques are used to calculate emissions from the site. These methods and their application to the site s emission sources are specified in Table 4.3. If significant changes are made to these methods, or new methods are identified that are determined to be appropriate for emission sources at the site, adjustments to the site s emissions caps, HEP and current actual emissions may be considered, depending on the nature and extent of the new methods or changes to the

current emission estimation techniques.

6.1.2. Change in list of criteria pollutants or National Ambient Air Quality Standards (NAAQS)-- If EPA adds, deletes, or modifies the list of criteria pollutants or NAAQSs, adjustments to the site s emissions caps, HEP, current actual emissions, and other changes to the PSD permit may be considered, depending on the reason for the change and its impact on the site s emission totals. If changes are made to incorporate the revision, Section 1 will also be revised to reflect the addition, deletion or modification of the pollutant.

6.1.3. Review of examples of control technology in 1.3.2(c) -- Controls listed in Subsection 1.3.2(c) represent good environmental engineering practice with regard to controlling air pollutants. Changes to this list may be considered, including evaluation of new control technology, to ensure that the section continues to represent good environmental engineering practice.

6.1.4. Adequacy of Section 4 requirements -- Section 4 (Monitoring, recordkeeping and reporting requirements) may be reviewed to ensure that it provides information necessary to evaluate the site s performance under the agreement. This section also may be reviewed to identify overlapping or unnecessary requirements.

6.1.5. Review Procedure for New Criteria Pollutant Regulations -- Subsection 1.2.2(c) describes the review and approval procedure for the emissions cap adjustment for new regulations. This procedure may be evaluated and changes to the procedure considered in order to facilitate timely and appropriate adjustments.

6.1.6. Review of Termination Criteria -- Section 8 specifies criteria subject to which the PSD permit would be terminated. These criteria may be evaluated and changes considered as deemed necessary.

6.1.7. Review of Modeling for Short Term PM-10 and SO_2 emissions -- Prior to the five-year review, Merck shall submit to the project stakeholders information necessary to perform short term PM-10 and SO_2 NAAQS modeling, similar in extent and detail to the modeling performed for the permit support documentation. This information shall include but not be limited to the current plant configuration with information on building locations and dimensions, information on emission sources including stack dimensions, exit gas parameters, and emission rates for actual operating conditions and worst case short-term (3 and 24-hour) operating conditions. If major changes have been made at the site not reflected in the most recent modeling analysis, Merck shall perform an updated modeling analysis if requested by EPA or VADEQ.

6.1.8. Review of the Determination that the Area is NO_x Limited for Ozone Formation -- If any project stakeholders present technical papers or studies that change the generally recognized determination that the area near the site, including the Shenandoah National Park, is NO_x-limited for ozone formation, changes to terms of the PSD permit may be considered.

6.1.9. Review of Periodic Review Criteria -- Section 6 specifies criteria by which the PSD permit shall be periodically reviewed. These criteria may be evaluated and changes considered as deemed necessary.

6.2. Review Triggered by Emission Levels

6.2.1. Review of Air Quality Related Values (AQRVs)

a. Trigger for AQRV Assessment: The AQRV assessment specified in this subsection shall be triggered upon either of the following events:

i. After installation of any individual new process or process modification that results in a net increase in the site s actual VOC emissions of 100 TPY or more. Net increase means the sum of emission increases and decreases occurring at the site resulting from the new or modified installation.

ii. After the first time the site-wide VOC emissions exceed two times the baseline (Table 1.1) VOC level (i.e., if site-wide VOC emissions reach 816 TPY).

b. AQRV Assessment: If an AQRV assessment is triggered in (a), VOC emission increases shall be reviewed to determine whether they are the cause of or significantly contribute to adverse impacts on any AQRVs at the Class I area (Shenandoah National Park). Merck shall be responsible for performing the assessment of VOC impacts on AQRVs using demonstrated methods for such assessments.

c. Mitigation Measures: If the project signatories agree that Merck s VOC emissions are the cause of adverse impacts on any AQRVs at the Class I area (Shenandoah National Park), Merck shall implement mitigation measures that are agreed to by the project signatories.

6.2.2. Review of Non-HAP VOCs -- No later than three months after the site-wide VOC emissions reach 125% of the baseline (Table 1.1) VOC level (i.e., if site-wide VOC emissions reach 510 TPY):

a. Merck shall provide to the project stakeholders the list of non-HAP VOCs that were emitted from the facility in the previous 12 months. EPA shall conduct a review of the scientific literature for any new information on the health effects of these compounds and provide such information to the project stakeholders.

b. Merck shall conduct a site-wide modeling assessment of non-HAP VOC emissions yielding average property line concentrations. These modeling results shall be compared to the Significant Ambient Air Concentrations (SAAC) established in the Virginia Air Regulations (9 VAC 5 Chapter 40, Part II, Article 3 (9 VAC 5-40-160 et seq.) and 9 VAC 5 Chapter 50, Part II, Article 3 (9 VAC 5-50-160 et seq.) except the most recent Threshold Limit Values published by the ACGIH shall be used in the SAAC calculations. If this assessment predicts an exceedance of the SAAC for any of the modeled substances, Merck shall either:

i. Demonstrate to the VADEQ s satisfaction that the applicable SAAC is inappropriate for the substance in question by showing that the emissions from the site produce no endangerment of human health; or

ii. Implement changes at the site resulting in ambient concentrations of the substance that are below the SAAC or resulting in such other ambient concentrations acceptable to the VADEQ.

Any actions pursuant to (i) or (ii) to resolve any SAAC exceedance shall be initiated within four months of reaching the VOC level that

triggered this subsection, and communicated to the project stakeholders.

c. Subsequent assessments specified in (a) and (b) shall be conducted if site-wide VOC emissions increase further whenever such incremental increases exceed 100 TPY (i.e., at VOC levels of 610 TPY, 710 TPY, 810 TPY, etc.). If 9 VAC 5 Chapter 40 Part II Article 3 or 9 VAC 5 Chapter 50 Part II Article 3 of the Virginia Air Regulations are significantly modified or rescinded, the project stakeholders shall consider an alternative system upon which to base this periodic evaluation. Unless the project signatories agree to change or eliminate this system, the requirements of this subsection shall remain in effect.

7. Duration of the PSD Permit

The PSD permit shall continue to be in effect unless terminated as specified in Section 8 or 11.

8. Termination of the PSD Permit

8.1. The PSD permit may be terminated as provided in 8.2 through 8.4 upon written notice for the following reasons only:

8.1.1. If the EPA or VADEQ determines that continuation of the PSD permit is an imminent and substantial endangerment to public health or welfare, or the environment.

8.1.2. If Merck knowingly falsifies emissions data.

8.1.3. If Merck fails to implement the powerhouse conversion project in accordance with Section 2.

8.1.4. If Merck receives four consent orders or two judgments adverse to Merck arising from non-compliance with this permit in a five year period that are deemed material.

8.1.5. If the total emissions cap is exceeded.

8.1.6. Upon full consent of all project signatories.

8.1.7. For other reasons not specified in Section 8.1 for which VADEQ has statutory authority to terminate the permit.

8.2. Force majeure exemption from Section 8.1.

8.2.1. A force majeure is defined as any event arising from causes not reasonably foreseeable and beyond the control of Merck, which cannot be overcome by due diligence and which delays or prevents performance by a date or manner required by this PSD permit.

8.2.2. Such force majeure events shall not cause termination of the PSD permit, providing that Merck complies with the notification requirements in 8.2.3.

8.2.3. Within seven calendar days after it becomes aware of an event which Merck claims constitutes a force majeure exemption from Subsection 8.1, Merck shall notify EPA and VADEQ. This notification shall include the estimated time anticipated for the delay, its cause, measures taken or to be taken to prevent or minimize the delay, and the estimated timetable for the implementation of these measures.

8.3. In the event of termination as specified in Subsection 8.1, the VADEQ or EPA shall provide the project signatories with written notice of its intent to terminate

the PSD permit. Within 30 calendar days of Merck s receipt of this notice, Merck 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 regulatory agency that provided written notice of its intent to terminate the permit, the action to terminate the PSD permit shall be withdrawn. Otherwise, the PSD permit is terminated as provided in Subsection 8.4.

8.4. If the notice of intent to terminate is not withdrawn by the enforcing agency as provided in Subsection 8.3, the agreement shall be terminated in the following manner:

8.4.1. Merck shall submit a revised Title V application under the then-applicable Title V program no later than 12 months after the notice of intent to terminate, or within some other reasonable shorter time period as agreed to by the Title V-implementing agency and Merck (called the interim period).

8.4.2. During this interim period Merck shall meet with the Title V-implementing agency to agree upon the appropriate applicable requirements to be included in the Title V application and draft permit.

8.4.3. During this interim period Merck shall abide by all terms of the PSD permit that are in effect at that time. If the site s actual 12-month rolling total of criteria pollutant emissions equals or exceeds the total emissions cap, increases of these emissions shall be allowed only with prior approval from the permitting authority(ies) and receipt of any necessary preconstruction permits.

8.4.4. Once the revised Title V permit application is submitted and deemed complete, the Title V-implementing agency shall issue an order stipulating that the site shall operate under the requirements as specified in the Title V application and in compliance with all applicable requirements. Upon issuance of the order the PSD permit would be terminated.

8.5. Termination of the PSD permit does not cancel Merck s obligation to complete any corrective actions relating to non-compliance under the PSD permit.

9. Inspection and Entry

9.1. Upon presentation of credentials and other documents as may be required by law, Merck shall allow authorized representatives of EPA and VADEQ to perform the following:

9.1.1. Enter upon the site

9.1.2. Have access to and copy at reasonable times any records that must be kept under the conditions of the PSD permit

9.1.3. Have access at reasonable times to batch and other plant records needed to verify emissions

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

9.1.5. Sample or monitor any substances or parameters at any location, during operating hours, for the purpose of assuring PSD permit compliance or as otherwise authorized by the Clean Air Act.

9.2. 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 PSD permit violation and assessment of civil penalties.

9.3. Such site, facility and equipment access, and sampling and monitoring shall be subject to Merck safety and industrial hygiene procedures, and Food and Drug Administration and Good Manufacturing Practice requirements in force at the site.

10. Reservation of Rights

10.1. Except as expressly provided in this PSD permit:

10.1.1. Each project signatory reserves all rights and defenses it may have, and

10.1.2. Nothing herein shall prevent EPA or VADEQ from taking administrative enforcement measures or seeking legal or equitable relief to enforce the terms of the PSD permit, including but not limited to the right to seek injunctive relief, and imposition of statutory penalties, fines and/or punitive damages.

10.2. Nothing herein shall be construed to limit the rights of EPA or VADEQ to undertake any criminal enforcement activity against Merck or any person.

10.3. Nothing herein shall be construed to limit the authority of EPA or VADEQ to undertake any actions in response to conditions which present an imminent and substantial endangerment to public health or welfare, or the environment.

10.4. Nothing herein shall be construed to limit Merck's rights to administrative and judicial appeal of termination actions in accordance with 9 VAC 5 Chapter 170, Part VIII of the State Air Pollution Control Board Regulations for the Control and Abatement of Air Pollution.

11. Transfer of Ownership

11.1. The terms of the PSD permit are transferable to a new owner upon sale of the site.

11.2. In the event of any change in ownership or control of the site, Merck shall notify the project stakeholders in writing no later than 10 days after the change. The notification shall include the name, address, telephone number of the transferee in interest, and the date of the transfer.

11.3. For the first 12 months after change in ownership or control of the site, the new owner shall submit the monthly 12-month rolling total of criteria pollutant emissions to the project signatories, in the same manner as specified in Section 4.

11.4. Within 12 months of the change in ownership or control of the site, the PSD permit shall be reviewed as specified in Section 6. Such review shall also include an affirmative renewal of the PSD permit by the project signatories. Affirmative renewal means that the PSD permit shall continue to be in effect if all project signatories (excluding Merck and including the new owner/operator) agree that the PSD permit should continue; otherwise, the PSD permit shall be terminated as specified in Subsection 8.4.

12. Definitions for Terms in the PSD Permit

12.1. 12-Month Rolling Total: The 12-month rolling total for an individual pollutant or the total of Section 1.1 pollutants is calculated on a monthly basis as the sum of all actual emissions of the respective pollutant(s) from the previous 12 months.

12.2. Completion of powerhouse conversion: the date upon which the new boilers are operational. This determination shall be made by Merck based on the boiler manufacturer s installation, startup and shakedown specifications.

12.3. Compliance date: the date upon which the site is required to take action in order to comply with a new regulation or a regulation to which it is newly subject.

12.4. Highest Emission Point (HEP): The highest 12-month rolling total of criteria pollutant emissions from the site since 12 months after completion of the powerhouse conversion project.

12.5. Process unit: (a) manufacturing equipment assembled to produce a single intermediate or final product, and (b) any combustion device.

12.6. Project stakeholders: employees of the project signatories to the Final Project Agreement, plus other parties as follows:

12.6.1. 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 Final Project Agreement. Community representatives are defined as local government and or community residents with an ongoing stake in the project, and

12.6.2. 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.

12.7. Responsible official: (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.

12.8. Signatories to the Final Project Agreement or project signatories: The U.S. Environmental Protection Agency (EPA), the Virginia Department of Environmental Quality (VADEQ), the Department of the Interior Federal Land Manager (FLM), the Rockingham County Board of Supervisors, and Merck & Co., Inc. All correspondence required by this PSD permit shall be directed to the individual representatives for each of these project signatories listed in Table 12.8. This table may be revised upon written notification to the project signatories.

12.9. Site: 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.

Table 1.1
Actual Criteria Pollutant Emissions from the Stonewall Site

Pollutant	1992 Actual Emissions (TPY)	1993 Actual Emissions (TPY)	Average of 1992 and 1993 (TPY)	Emission Cap Established in Subsection 1.2.1
SO_2	714	723	719	539
NO_x	293	290	291	262
CO	44	42	43	NA
PM-10	42	42	42	42
VOC	442	374	408	NA
Total criteria emissions	1535	1471	1503	1202

Table 1.3.3.
Operation of Listed Control Equipment

Emission Unit	Control Device	Pollutant
General requirement for all air pollution control (APC) equipment: Maintain APC equipment in proper working order		
Diesel generator	NO_x control	NO_x
Solid waste incinerator	Afterburner	VOCs
Sludge Dryer	Dust collectors (DC-383, DC-384)	PM-10
	Venturi scrubber (VS-390)	PM-10
Sludge incinerator	Venturi scrubber (SCB-290)	PM-10
Solvent Recovery	Venturi scrubber in solvent recovery (SCR-1000)	VOCs
CRIXIVAN®	Fabric filter boxes (Finishing) (VF-121, VF-185)	PM-10
	Thermal oxidizer (TOU-2542)	VOCs
	Scrubber (SCR-2546)	VOCs and acid gases
	Secondary brine condensers in solvent recovery (CN-102, CN-505/506, CN-702)	VOCs
	Conservation Vents (Bulk Storage Tanks)	VOCs
Lovastatin	Bulk storage tank conservation vent	VOCs
	Secondary brine condensers in solvent recovery (CN-203) and Building 43 (CN-911)	VOCs

Table 4.2
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section A: Site-Wide Criteria Pollutant Emissions						
Cap calculations	A.1	Monthly	Monthly	Monthly	Record	12-month rolling total site wide criteria pollutant emissions
	A.2	Monthly	Monthly	Monthly	Record	12-month rolling total site wide SO_2, NO_x, PM-10, CO, and VOC emissions, respectively
	A.3	Monthly	Monthly	Monthly	Record	Total emissions cap, SO_2 cap, NO_x cap, PM-10 cap
	A.4	Monthly	Monthly	Monthly	Record	Current HEP
	A.5	Monthly	Monthly	Monthly	Record	Current reporting tier as defined in Section 4.
	A.6	Semi-annually	Semi-annually	Monthly	Report	12-month rolling total site wide criteria pollutant emissions for each month covered by report.
	A.7	Semi-annually	Semi-annually	Monthly	Report	12-month rolling total SO_2, NO_x, PM-10, CO, and VOC emissions, respectively for each month covered by report.
	A.8	Annually	Semi-annually	Monthly	Report	Total criteria pollutant emissions and SO_2, NO_x, and PM-10 emissions prevented from XL project since last report (difference between cap/subcap and actuals)
	A.9	Annually	Semi-annually	Monthly	Report	Total criteria pollutant emissions and SO_2, NO_x, and PM-10 emissions prevented from XL project since start of PSD permit (cumulative difference between cap and actuals)
	A.10	Annually	Semi-annually	Monthly	Report	Reporting tier as defined in Section 4 for each month covered by report.
	A.11	Within one month of changing from a lower tier to a higher tier			Report	Reporting tier as defined in Section 4.

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section A: Site-Wide Emissions (continued)						
Cap adjustments	A.12	Monthly	Monthly	Monthly	Record	Any adjustments to total emissions cap or individual caps
	A.13	Annually	Semi-annually	Monthly	Report	Any adjustments to total emissions cap or individual caps, and explanation for adjustment
	A.14	Upon compliance date of new regulation			Record	Record decision whether to implement regulation as written or adjust cap under Subsection 1.2.2.
	A.15	120 or 90 days prior to compliance date of new regulation selected for cap adjustment as required by Subsection 1.2.2(c).			Report	Report total criteria pollutant reduction resulting from regulation, HEP or alternate emission rate, and basis for estimate
Subsection 1.3.2 Installations	A.16	Upon operation of any modification or new installation			Record	Calculations determining whether the process modification or new installation triggers 1.3.2(b) significance levels
	A.17	Within 45 days of operation of any significant modification or significant new installation			Report	Submit report describing the significant modification or significant new installation (as defined in 1.3.2), and the controls, pollution prevention or other technology employed to meet the requirements of 1.3.2. If the method employed is not one of the methods listed in 1.3.2(c), include an explanation for the technology selected.

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section A: Site-Wide Emissions (continued)						
	A.18	Within 45 days of operation of any significant modification or significant new installation			Report	Submit report providing the following information: a schematic diagram showing the type and sequence of new equipment installed or modified, equipment identification numbers, location of the new installation or modification on the plant site, air pollution control equipment associated with the new installation or modification, and the total emissions of each criteria pollutant emitted from each piece of new or modified equipment.
Operation of listed controls (1.3.3)	A.19	Ongoing	Ongoing	Ongoing	Record	Record time control equipment listed in Table 1.3.3. is not operating while the controlled emissions unit is operating.
	A.20	Annually	Annually	Annually	Report	Percent time that each control device listed in Table 1.3.3. operated over the previous year.
Modeling Parameters	A.21	Upon request within reasonable time period			Report	Stack parameters and modeling inputs for sources of PM-10, NO_x and SO_2.

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section B: Powerhouse						
Natural Gas-Fired Boilers	B.1	Within 180 days of powerhouse conversion			Monitor	Perform stack test to quantify criteria pollutant emissions
	B.2	Continuously	Continuously	Continuously	Monitor and Record	NO_x and opacity using CEMs or PEMs.
	B.3	Monthly	Monthly	Monthly	Monitor and Record	Type and amount of fuel used
	B.4	Monthly	Monthly	Monthly	Record	Emissions based on stack test, NO_x CEM/PEM, emission factors and fuel usage
	B.5	Annually	Semi-annually	Monthly	Report	Emissions based on stack test, NO_x CEM/PEM, emission factors and fuel usage
	B.6	Monthly	Monthly	Monthly	Record	Percent time burning natural gas and backup fuel
	B.7	Annually	Semi-annually	Monthly	Report	Percent time burning natural gas and backup fuel
Backup oil unit	B.8	Monthly	Monthly	Monthly	Monitor and Record	Amount and type of fuel used
	B.9	Monthly	Monthly	Monthly	Record	Emissions based on emission factors and fuel usage

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section C: Trash Incinerator and Sludge Incinerator						
Both units	C.1	Monthly			Record	Emissions based on emission factors and operation schedule
	C.2	Annually			Report	Emissions based on emission factors and operation schedule
	C.3		Monthly	Monthly	Monitor	Amount and type of fuel used
	C.4		Monthly	Monthly	Monitor	Waste throughput
	C.5		Monthly		Record	Emissions based on emission factors, fuel usage and waste throughput
	C.6		Semi-annually		Report	Emissions based on emission factors, fuel usage and waste throughput
	C.7			One-time[4]	Monitor	Perform stack test to quantify criteria pollutant emissions
	C.8			Monthly	Record	Emissions based on stack test, fuel usage and waste throughput
	C.9			Monthly	Report	Emissions based on stack test, fuel usage and waste throughput
Trash incinerator	C.10	Continuously	Continuously	Continuously	Monitor	Afterburner temperature and opacity
	C.11	Continuously	Continuously	Continuously	Record	Afterburner temperature and opacity

[4] Within 6 months of reaching Tier III for the first time. A stack test performed no more than 5 years prior to reaching Tier III may be used in place of a new test provided that the emission controls and operating conditions are still representative of those under which the prior test was conducted.

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section D: Emergency Generators						
All units	D.1	Monthly			Record	Emissions based on emission factors, operation schedule and any non-scheduled event requiring operation of a unit for five days or more.
	D.2	Annually			Report	Emissions based on emission factors, operation schedule and any non-scheduled event requiring operation of a unit for five days or more.
	D.3		Monthly	Monthly	Monitor and Record	Time of operation
	D.4		Monthly	Monthly	Monitor and Record	Amount and type of fuel used
	D.5		Monthly	Monthly	Record	Emissions based on emission factor and fuel usage
	D.6		Semi-annually	Monthly	Report	Emissions based on emission factor and fuel usage
Powerhouse generator	D.7	Annually	Annually	Annually	Monitor	Verify timing retarded 4 degrees from top dead center

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section E: Production Process Units						
	E.1	Monthly	Monthly	Monthly	Record	Changes to the process that affect the emission factor
	E.2	Monthly	Monthly	Monthly	Record	Maintain current process emission factors
	E.3	Monthly	Monthly	Monthly	Monitor and Record	WWTP influent flow, temperature and VOC constituent concentrations
	E.4	Monthly	Monthly	Monthly	Monitor and Record	Number of production units
	E.5	Monthly	Monthly	Monthly	Record	Emissions based on emission factor and number of production units
	E.6	Annually	Semi-annually	Monthly	Report	Emissions based on emission factor and number of production units
	E.7		Annually	Semi-annually	Report	Summary of changes to emission factors based on process modifications
	E.8	Annually	Annually	Annually	Report	Basis for point source emission factors (see example 1 below)

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section E: Production Process Units (continued)						
	E.9	Within 180 days of start-up of new unit operation			Record	Emission factor verification study for unit operations not included in the following list: Fill, Evacuation, Gas Sweep, Heat, Gas Evolution, Vacuum Distillation, Vacuum Drying, Tank Breathing.

Example 1
Basis for Process Vent Emission Factor
For Each Process:

Step Number	Vessel I.D.	VOC Emissions (lb/step)
1	RE-101	0.1
2	RE-101	2.5
3	RE-101	20
4	TA-105	0.2
. . .	. . .	. . .
80	TA-308	0.3
Total		95.2 lb/production unit

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section F: Criteria Pollutant Control Equipment						
Sludge Dryer dust collectors (DC-383, DC-384)	F.1	Continuously	Continuously	Continuously	Monitor	Differential pressure drop
	F.2	Once per day	Once per day	Once per day	Record	Differential pressure drop
Sludge Dryer venturi scrubber (VS-390)	F.3	Continuously	Continuously	Continuously	Monitor	Pressure drop and liquid flow
	F.4	Once per day	Once per day	Once per day	Record	Pressure drop and liquid flow
Sludge incinerator venturi scrubber (SCB-290)	F.5	Continuously	Continuously	Continuously	Monitor	Pressure drop and liquid flow
	F.6	Once per day	Once per day	Once per day	Record	Pressure drop and liquid flow
CRIXIVAN® fabric filters (finishing) (VF-121, VF-185)	F.7	Continuously			Monitor	Differential pressure drop across filter
	F.8	Once per batch			Record	Differential pressure drop across filter
CRIXIVAN® thermal oxidizer (TOU-2542)	F.9	Continuously			Monitor and Record	Combustion chamber temperature
CRIXIVAN® scrubber (SCR-2546)	F.10	Continuously			Monitor	Liquid flow and differential pressure drop
	F.11	Once per batch			Record	Liquid flow and differential pressure drop

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section F: Criteria Pollutant Control Equipment (continued)						
CRIXIVAN® secondary brine condensers in solvent recovery (CN-102, CN-505, CN-506, CN-702)	F.12	Continuously	Continuously	Continuously	Monitor	Exit vapor temperature or coolant flow and coolant exit temperature
	F.13	Once per batch	Once per batch	Once per batch	Record	Exit vapor temperature or coolant flow and coolant exit temperature
Lovastatin secondary brine condenser in solvent recovery (CN-203) and Building 43 (CN-911)	F.14	Continuously	Continuously	Continuously	Monitor	Exit vapor temperature or coolant flow and coolant exit temperature
	F.15	Once per batch	Once per batch	Once per batch	Record	Exit vapor temperature or coolant flow and coolant exit temperature
Solvent recovery venturi scrubber (SCR-1000)	F.16	Continuously			Monitor	Liquid flow and differential pressure drop
	F.17	Once per batch			Record	Liquid flow and differential pressure drop
Carbidopa thermal oxidizer (RE-3500)	F.18	Continuously			Monitor	Combustion chamber temperature
	F.19	Once per batch			Record	Combustion chamber temperature
Carbidopa packed bed scrubber (SCR-634, SCR-3500)	F.20	Continuously			Monitor	Liquid flow and pH
	F.21	Once per batch			Record	Liquid flow and pH

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section F: Criteria Pollutant Control Equipment (continued)						
Units that would otherwise be regulated under 40 CFR 264 Subpart AA or 265 Subpart AA controlled by a condenser	F.22	Continuously	Continuously	Continuously	Monitor	Coolant flow and coolant outlet temperature
	F.23	Once per batch	Once per batch	Once per batch	Record	Coolant flow and coolant outlet temperature
Units that would otherwise be regulated under 40 CFR 264 Subpart AA or 265 Subpart AA controlled by a thermal oxidizer	F.24	Continuously			Monitor and Record	Combustion chamber temperature
VOC and volatile organic[5] bulk storage tanks >=10,000 gal capacity: conservation vent	F.25	Annually	Annually	Annually	Monitor	Verify conservation vent pressure setting at or above 0.030 psi
New condensers added under 1.3.2 of the permit	F.26	Continuously	Continuously	Continuously	Monitor	Coolant flow and coolant outlet temperature
	F.27	Once per batch	Once per batch	Once per batch	Record	Coolant flow and coolant outlet temperature
New non-catalytic thermal oxidizers added under 1.3.2 of the permit	F.28	Continuously			Monitor and Record	Combustion chamber temperature

[5] As defined in 40 CFR 264 and 265.

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section F: Criteria Pollutant Control Equipment (continued)						
New catalytic thermal oxidizers added under 1.3.2 of the permit	F.29	Continuously			Monitor and Record	Inlet temperature and temperature increase across catalyst bed.
New scrubbers added under 1.3.2 of the permit	F.30	Continuously			Monitor	Scrubber water flow and differential pressure
	F.31	Once per batch			Record	Scrubber water flow and differential pressure
New carbon adsorption systems added under 1.3.2 of the permit	F.32	Within 60 days of unit s initial startup			Record	Establish appropriate regeneration cycle based on breakthrough rate, and performance indicator (e.g., online time, number of batches, or breakthrough indicator)
	F.33	Once per batch			Record	Carbon performance indicator
New regenerative carbon adsorption systems added under 1.3.2 of the permit	F.34	Once per regeneration cycle			Monitor and Record	Regeneration medium mass flow during regeneration and carbon bed temperature after regeneration
New dust collection systems added under 1.3.2 of the permit	F.35	Continuously			Monitor	Differential pressure across filter
	F.36	Once per batch			Record	Differential pressure across filter

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section F: Criteria Pollutant Control Equipment (continued)						
Each condenser at site with uncontrolled emissions >8000 lb/yr VOCs	F.37		Continuously	Continuously	Monitor	Coolant flow and coolant outlet temperature
	F.38		Once per batch	Once per batch	Record	Coolant flow and coolant outlet temperature
All non-catalytic thermal oxidizers at site	F.39		Continuously	Continuously	Monitor and Record	Combustion chamber temperature
All catalytic thermal oxidizers at site	F.40		Continuously	Continuously	Monitor and Record	Inlet temperature and temperature increase across catalyst bed.
All scrubbers at site	F.41		Continuously	Continuously	Monitor	Scrubber water flow and differential pressure
	F.42		Once per batch	Once per batch	Record	Scrubber water flow and differential pressure
All carbon adsorption systems at site	F.43		Within 60 days of unit s initial startup		Record	Establish appropriate regeneration cycle based on breakthrough rate, and performance indicator (e.g., online time, number of batches, or breakthrough indicator)
	F.44		Once per batch	Once per batch	Record	Carbon performance indicator
All regenerative carbon adsorption systems at site	F.45		Once per regeneration cycle	Once per regeneration cycle	Monitor and Record	Regeneration medium mass flow during regeneration and carbon bed temperature after regeneration

Table 4.2 (continued)
Monitoring, Recordkeeping and Reporting Requirements

Emission Unit		Tier I Frequency	Tier II Frequency	Tier III Frequency	Monitor/Record /Report	Requirement
Section F: Criteria Pollutant Control Equipment (continued)						
All dust collection systems at site	F.46		Continuously	Continuously	Monitor	Differential pressure across filter
	F.47		Once per batch	Once per batch	Record	Differential pressure across filter
Each condenser at site with uncontrolled emissions >4000 lb/yr VOCs	F.48			Continuously	Monitor	Coolant flow and coolant outlet temperature
	F.49			Once per batch	Record	Coolant flow and coolant outlet temperature
All condensers at site with uncontrolled emissions >4000 lb/yr VOCs	F.50			One-time[6]	Monitor/Record	Confirm condenser performance with engineering calculation tool or stack test
All thermal oxidizers at site	F.51			One-time[6]	Monitor and Record	Perform stack test on unit to determine criteria pollutant emissions
All scrubbers at site	F.52			One-time[6]	Monitor/Record	Confirm scrubber performance with engineering calculation tool or stack test
All carbon adsorption systems at site	F.53			One-time[6]	Monitor/Record	Confirm carbon system performance with engineering calculation tool or stack test
All dust collection systems at site	F.54			One-time[6]	Monitor/Record	Confirm dust collection system performance with engineering calculation tool or stack test

[6] Within 6 months of reaching Tier III for the first time for existing equipment, and within 3 months of commencement of operation for new equipment. A stack test performed no more than 5 years prior to reaching Tier III may be used in place of a new test provided that the emission controls and operating conditions are still representative of those under which the prior test was conducted..

Table 4.3
Calculation Techniques Used to Determine Site-Wide Emissions[7]

Emission Sources	Methods of Calculation				
	VOC	**SO_2**	**PM-10**	**NO_x**	**CO**
Process Vents	1,2	2	2	2	2
Internal Combustion Sources	2,6,7	2,6,7	2,6,7	2,6,7	2,6,7
External Combustion Sources	2,6,9	2,6,9	2,6,9	2,6,8,9	2,6,9
Natural Gas-Fired Boilers	2,6,10	2,6,10	2,6,10	2,6,8,10	2,6,10
VOC Bulk Storage Tanks	1,2	2	2	2	2
Solvent Recovery	2,4	2	2	2	2
Equipment Leaks	2,3	2	2	2	2
Wastewater Treatment	2,5	2	2	2	2

Key to Methods of Calculation:

1. 1978 Control Techniques Guideline, EPA; MacEmit Model; EMIT 10
2. Engineering Calculations
3. Site - Specific Emission Factors based on site-generated monitoring data approved for use by the VADEQ.
4. B-JAC Condenser Model
5. Toxchem Model, approved for use by the EPA
6. EPA AP - 42 Emissions Factors. (5th Edition, 1995)
7. Vendor Emission Data.
8. Actual NO_x data from CEMs or PEMs.
9. Available stack test data from comparable sources.
10. Stack test performed on unit.

[7] For additional information about emission calculation techniques, please refer to the permit support document.

Table 12.8
Individual Signatory Representatives

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Mr. William Kyger	Chairman	Rockingham County Board of Supervisors	P.O. Box 1252, Harrisonburg, VA 22801	540-433-5626
Mr. Tedd Jett	Environmental Engineering Manager	Environmental Engineering Department Merck & Co., Inc.	P.O. Box 7 Elkton, VA 22827-0007	540-298-4869