Form: TH- 05

Virginia Regulatory Town Hall

Periodic Review of Existing Regulations
Agency Background Document

Agency Name:	State Air Pollution Control Board
Regulation Title:	Variance for Merck Stonewall Plant
Subtitle:	
VAC Number:	9 VAC 5 Chapter 190 (9 VAC 5-190-10 et seq.)
Date:	

This information is required pursuant to the Administrative Process Act § 9-6.14:25 and Executive Order Twenty-Five (98) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

Summary

Please provide a brief summary of the regulation and its purpose. There is no need to state each provision, instead give a general description of the regulation.

The purpose of the regulation is to allow Merck to use compliance with a PSD permit as an alternate demonstration of compliance with provisions of the regulations of the State Air Pollution Control Board. The regulation establishes a variance from most regulatory requirements of the Board for the Stonewall Plant operated by Merck and Co., Inc. and located in Elkton, Virginia. The variance affects other regulations of the Board pertaining to:

1. Major and Minor New Source Review Permitting and Registration
2. Virginia Air Toxics Regulations
3. Notification, Records and Reporting
4. Emission Standards for General Process Operations, Incinerators and Fuel Burning Equipment
5. Compliance and Monitoring
6. Certain provisions of New Source Performance Standards (NSPS)

7. Certain provisions of Federal Operating Permit regulations

8. Facility and Control Equipment Malfunction Reporting

9. Control Programs

10. Compliance Monitoring and Performance Testing

Additionally, the variance contains provisions regarding procedures for modifying the PSD permit.

The alternate regulatory system that would be established under the Order addresses only the pollutants identified in the permit (generally the criteria pollutants with the exception of lead). Merck will fully comply with the forthcoming Maximum Achievable Control Technology (MACT) standard for the pharmaceutical industry. Merck will also be required to obtain a Title V operating permit, pursuant to the applicable Title V program in the SAPCB Regulations.

Legal Requirements

Please identify the state and/or federal source of the legal requirements that necessitate promulgation of the regulation. The discussion of these requirements should include a description of their scope and the extent to which the requirements are mandatory or discretionary. Full citations for the legal requirements and, if available, web site addresses for locating the text of the cited legal provisions should be provided.

Federal Requirements

Federal Clean Air Act (CAA):
http://www.epa.gov/ttn/oarpg/gener.html
Code of Federal Regulations (CFR):
http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html
Federal Register (FR):
http://www.gpo.gov/su_docs/aces/aces140.html

Among the primary goals of the federal Clean Air Act are the attainment and maintenance of the National Ambient Air Quality Standards (NAAQS) and the prevention of significant deterioration (PSD) of air quality in areas cleaner than the NAAQS.

The NAAQS, developed and promulgated by the U.S. Environmental Protection Agency (EPA), establish the maximum limits of pollutants that are permitted in the outside ambient air. EPA requires that each state submit a plan (called a State Implementation Plan or SIP), including any laws and regulations necessary to enforce the plan, that shows how the air pollution concentrations will be reduced to levels at or below these standards (attainment). Once the pollution levels are within the standards, the SIP must also demonstrate how the state will maintain the air pollution concentrations at the reduced levels (maintenance).

The PSD program is designed to protect air quality in areas where the air is cleaner than required by the NAAQS. The program has three classifications for defining the level of allowable degradation: Class I is the most stringent classification, allowing for little additional pollution, while Class III allows the most. All of Virginia is classified at the moderate level, Class II, with the exception of two Class I federal lands.

A SIP is the key to the state's air quality programs. The Clean Air Act is specific concerning the elements required for an acceptable SIP. If a state does not prepare such a plan, or EPA does not approve a submitted plan, then EPA itself is empowered to take the necessary actions to attain and maintain the air quality standards--that is, it would have to promulgate and implement an air quality plan for that state. EPA is also, by law, required to impose sanctions in cases where there is no approved plan or the plan is not being implemented, the sanctions consisting of loss of federal funds for highways and other projects and/or more restrictive requirements for new industry. Generally, the plan is revised, as needed, based upon changes in the federal Clean Air Act and its requirements.

The basic approach to developing a SIP is to examine air quality across the state, delineate areas where air quality needs improvement, determine the degree of improvement necessary, inventory the sources contributing to the problem, develop a control strategy to reduce emissions from contributing sources enough to bring about attainment of the air quality standards, implement the strategy, and take the steps necessary to ensure that the air quality standards are not violated in the future.

The heart of the SIP is the control strategy. The control strategy describes the emission reduction measures to be used by the state to attain and maintain the air quality standards. There are three basic types of measures: stationary source control measures, mobile source control measures, and transportation source control measures. Stationary source control measures are directed at limiting emissions primarily from commercial/industrial facilities and operations and include the following: emission limits, control technology requirements, preconstruction permit programs for new industry and expansions, and source-specific control requirements. Stationary source control measures also include area source control measures which are directed at small businesses and consumer activities. Mobile source control measures are directed at tailpipe and other emissions primarily from motor vehicles and include the following: Federal Motor Vehicle Emission Standards, fuel volatility limits, reformulated gasoline, emissions control system anti-tampering programs, and inspection and maintenance programs. Transportation source control measures limit the location and use of motor vehicles and include the following: carpools, special bus lanes, rapid transit systems, commuter park and ride lots, bicycle lanes, signal system improvements, and many others.

Federal guidance on states' approaches to the inclusion of control measures in the SIP has varied considerably over the years, ranging from very general in the early years of the Clean Air Act to very specific in more recent years. Many regulatory requirements were adopted in the 1970s when no detailed guidance existed. The legally binding federal

mandate for these regulations is general, not specific, consisting of the Clean Air Act's broad-based directive to states to attain and maintain the air quality standards. However, in recent years, the Clean Air Act, along with EPA regulations and policy, has become much more specific, thereby removing much of the states' discretion to craft their own air quality control programs.

Generally, a SIP is revised, as needed, based upon changes in air quality or statutory requirements. For the most part the SIP has worked, and the standards have been attained for most pollutants in most areas.

EPA has promulgated a site-specific PSD rule (40 CFR 52.2454) for the Merck Stonewall Plant in order to implement the XL project for the site. 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.

On November 24, 1997 (62 FR 62594), EPA delegated the authority to implement and enforce the site-specific PSD rule to the Commonwealth.

State Requirements

Code of Virginia:
http://leg1.state.va.us/000/cod/codec.htm
Virginia Administrative Code (VAC):
http://leg1.state.va.us/000/reg/toc.htm

Code of Virginia § 10.1-1307 A provides that the board may, among other activities, develop a comprehensive program for the study, abatement, and control of all sources of air pollution in the Commonwealth.

Code of Virginia § 10.1-1308 provides that the board shall have the power to promulgate regulations abating, controlling, and prohibiting air pollution throughout or in any part of the Commonwealth in accordance with the provisions of the Administrative Process Act.

Code of Virginia § 10.1-1307 C specifies that the board may grant local variances from regulations and issue orders to that effect only after a public hearing has been conducted pursuant to the public advertisement of the hearing and the public has been given the opportunity to comment on the variance.

Comparison with Statutory Requirements

No provision of the regulation exceeds the specific minimum requirements of any legally binding state or federal mandate. An explanation as to how this conclusion was reached is set forth below.

The agency performed an analysis to determine if statutory mandates justify continuation of the regulation. The analysis revealed that statutory justification does exist for the

regulation. The regulation (variance) was adopted in order to implement the policy set forth in the Virginia Air Pollution Control Law and to fulfill the Commonwealth's responsibilities under the federal Clean Air Act to provide a legally enforceable State Implementation Plan for the control of criteria pollutants, specifically (i) to implement the XL project for the Merck Stonewall Plant in the Commonwealth and (ii) to provide the legal authority to implement and enforce the site-specific EPA PSD rule thus allowing the Commonwealth to accept delegation from EPA.. These statutes still remain in force with the provisions that initiated adoption of the regulation still intact.

Analysis reveals that the regulation is consistent with applicable state and federal regulations, statutory provisions, and judicial decisions. Factors and circumstances (federal statutes, original intent, state air quality program, and air pollution control methodology and technology) which justified the original issuance of the regulation have not changed to a degree that would justify a change to the basic requirements of the regulation.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. If no public comment was received, please include a statement indicating that fact

SUBJECT: General

COMMENTER: Merck & Co., Inc. and the Virginia Manufacturers Association

TEXT: We are commenting on a particular section of the regulations of great importance to Merck, cited at 9 VAC 5 Chapter 190, the Variance for Merck Stonewall Plant. In 1997, the Merck Stonewall Plant became one of the first facilities in the United States, and the only one in Virginia, to successfully complete a Final Project Agreement (FPA) with the U.S. Environmental Protection Agency and other stakeholders (Virginia DEQ, National Park Service and Rockingham County) under EPA's Project XL. This unique and innovative agreement enabled the implementation of a new and more flexible form of regulation of the emissions of criteria air pollutants from the facility. The agreement assured superior environmental protection while affording Merck with increased operating flexibility in the competitive, global pharmaceutical marketplace.

One of the fundamental building blocks on which the FPA was predicated is the variance embodied in 9 VAC 5 Chapter 190 of the Regulations for the Control and Abatement of Air Pollution. The variance, along with a site-specific federal rulemaking codified at 40 CFR 52.2454 and several sections of 40 CFR Parts 60, 264 and 265, authorized DEQ to issue a PSD permit to the Stonewall Plant under which the FPA is being implemented. The variance at 9 VAC 5 Chapter 190 is as critically important today as it was back in 1997 to the continued success of the Merck XL project.

The Governor's Executive Order 25 (98) requires state agencies to determine whether regulations should be "terminated, amended or retained in their current form". DEQ is soliciting public comment "regarding whether the regulations meet their established goals and whether the regulations are written clearly and easily understandable by affected persons". The regulation at 9 VAC 5 Chapter 190 is clearly written and has accomplished the goal of establishing a state regulatory foundation for the Merck PSD permit. The permit has brought about the conversion of Merck's coal-burning powerhouse to natural gas and the associated significant emissions reductions, established a cap on sitewide emissions of criteria pollutants that assures a permanent, minimum 300 TPY reduction and provided the Plant with the flexibility to make changes to its operations without prior approval.

We strongly recommend that the Board retain the regulation at 9 VAC 5 Chapter 190 in its current form so that it may continue to serve its intended function as a critical element of the foundation for the Merck XL project.

RESPONSE: Support for retention of the regulation is appreciated.

Effectiveness

Please provide a description of the specific and measurable regulatory goals of the regulation. Detail the effectiveness of the regulation in achieving such goals.

The regulation has been effective in achieving its specific and measurable goals, which are as follows:

1. To protect public health and welfare with the least possible cost and intrusiveness to the citizens and businesses of the Commonwealth.

2. To allow variance from the regulations in such a manner as to enable operational flexibility while protecting public health and welfare.

Need

Please provide the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens or is essential for the efficient and economical performance of an important governmental function. Include a discussion of the problems the regulation's provisions are intended to solve.

This regulation establishes a variance from most regulatory requirements of the State Air Pollution Control Board for the Stonewall Plant operated by Merck and Co., Inc. and located in Elkton, Virginia. The variance is part of an alternative permitting program known as Project XL. Project XL - for "eXcellence and Leadership" - is a central part of the National Performance Review's and EPA's effort to reinvent environmental protection.

Project XL is designed to enable a limited number of regulated entities to gain more flexible permitting arrangements in return for superior environmental benefit. Project XL participants must develop alternative pollution reduction strategies pursuant to stringent criteria and apply for acceptance into the program. They must have full support of affected Federal, State and Tribal agencies to be selected.

Once accepted, participants must negotiate a project agreement with a group of stakeholders representing regulatory authorities and concerned citizens. The stakeholder group for negotiating Merck's Final Project Agreement consisted of neighboring citizens and representatives from: DEQ, U.S. Environmental Protection Agency (EPA), U.S. Department of Interior, and Rockingham County Board of Supervisors.

The intended variance is necessary to enable DEQ to implement Merck's Project XL Agreement. The variance will allow DEQ to accept the PSD permit in lieu of otherwise applicable regulations, and allow Merck to operate within their PSD permit without obtaining additional permits which would otherwise be required.

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

To remain competitive in the worldwide pharmaceutical industry, the Merck Stonewall Plant must respond rapidly to changing market conditions and product demands. The air permitting regulations that govern modifications at the facility require that most changes to a manufacturing process be reviewed and approved in advance by DEQ. Even small changes may require extensive review due to the complexity of the Regulations and Merck's proximity to the Shenandoah National Park.

For their XL Project, Merck proposes to replace many individual emission limits with one plantwide cap on total emissions of criteria pollutants. The proposed plantwide cap on all criteria pollutants will represent a 20% reduction below recent actual emission rates. This will be accomplished by replacing existing coal fired boilers with new natural gas/ distillate oil fired boilers. The permit will also establish subcaps on SO_2, NO_X, and PM-10. Because there will be no subcap on VOC and CO, emissions of those pollutants may increase above actual recent levels, up to the limit established by the plantwide criteria pollutant cap. In exchange for the proposed reduction in emissions, Merck would be free to make changes in equipment and processes without obtaining further permits.

The powerhouse conversion to which Merck has agreed under the proposed PSD permit will achieve a significant upfront reduction of SO_2 and NO_X. Besides the reduction in criteria pollutants resulting from the Project, the conversion to natural gas will also result in approximately 47 TPY reduction in hazardous air pollutants (HAPs), specifically hydrogen chloride and hydrogen fluoride -- two HAPs that are generated by burning coal, and which 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.

Alternatives

Please describe the process by which the agency has considered, or will consider, less burdensome and less intrusive alternatives for achieving the need. Also describe, to the extent known, the specific alternatives that have been considered and will be considered to meet the need, and the reasoning by which the agency has rejected any of the alternatives considered.

Alternatives have been considered by the Department to meet the need. The Department has determined that retention of the regulation (the first alternative) is appropriate, as it is the least burdensome and least intrusive alternative that fully meets the statutory requirements and need for the regulation. The alternatives considered by the Department, along with the reasoning by which the Department has rejected any of the alternatives considered, are discussed below.

1. Retain the regulation without amendment. This option was chosen because the current regulation provides the least onerous method for complying with the minimum requirements of the legal mandates.

2. Make alternative regulatory changes to those required by the provisions of the legally binding state or federal mandates. This option was not chosen because it could result in the imposition of requirements that place unreasonable hardships on the regulated community without justifiable benefits.

3. Repeal the regulation or amend it to satisfy the provisions of the legally binding state or federal mandates. This option was not chosen because the regulation is effective in meeting its goals and already satisfies those mandates.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The Department, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the regulation on the institution of the family and family stability including to what extent the regulation will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment: 4) increase or decrease disposable family income.

It is not anticipated that the regulation will have a direct impact on families. However, there will be positive indirect impacts in that the regulation will ensure that the Commonwealth's air pollution control regulations will function as effectively as possible, thus contributing to reductions in related health and welfare problems.

Recommendation

Please state whether the agency is recommending the regulation be retained and the reasons such a recommendation is being made.

The regulation satisfies the provisions of the legally binding state or federal requirements and is effective in meeting its goals; therefore, it is recommended that the regulation be retained without amendment.