

## § 52.2452

## 40 CFR Ch. I (7-1-10 Edition)

### § 52.2452 Visibility protection.

(a) The requirements of section 169A of the Clean Air Act are not met, because the plan does not include approvable procedures for protection of visibility in mandatory Class I Federal areas.

(b) Regulation for visibility monitoring. The provisions of § 52.26 are hereby incorporated and made a part of the applicable plan for the State of Virginia.

(c) *Long-term strategy.* The provisions of § 52.29 are hereby incorporated and made part of the applicable plan for the State of Virginia.

[50 FR 28553, July 12, 1985, as amended at 52 FR 45137, Nov. 24, 1987]

### § 52.2453 Requirements for state implementation plan revisions relating to new motor vehicles.

Virginia must comply with the requirements of § 51.120 with respect to the portion of Virginia that in 1990 was located in the Consolidated Metropolitan Statistical Area containing the District of Columbia.

[60 FR 4738, Jan. 24, 1995]

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

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

(2) This section sets forth the prevention of significant deterioration of air quality preconstruction review requirements for the following pollutants only: carbon monoxide, nitrogen oxides, ozone (using volatile organic compounds as surrogate), particulate matter with an aerodynamic diameter less than 10 microns (PM<sub>10</sub>), and sulfur dioxide. This section applies in lieu of § 52.21 for the pollutants identified in this paragraph as well as particulate matter, but not for particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 microns (PM<sub>2.5</sub>) regulated as PM<sub>2.5</sub>; however, the preconstruction review requirements of § 52.21, or other preconstruction review

requirements that the Administrator approves as part of the plan, shall remain in effect for any pollutant which is not specifically identified in this paragraph and is subject to regulation under the Act.

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

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

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

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

*Permitting authority* means either of the following:

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

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

*Process unit* means:

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

(2) Any combustion device.

*Responsible official* means:

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

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

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

(ii) The authority to sign documents has been assigned or delegated to such representative in accordance with procedures of the business entity.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) *Installation of controls for significant modifications and significant new installations.* (i) This paragraph applies to significant modifications and significant new installations. Significant modifications for the purposes of this section are defined as changes to an existing process unit that result in an increase of the potential emissions of the process unit, after consideration of existing controls, of more than the significance levels listed in paragraph (e)(4)(ii) of this section. Significant new installations for the purposes of this section are defined as new process units with potential emissions before

controls that exceed the significance levels listed in paragraph (e)(4)(ii) of this section. For purposes of this section, potential emissions means process unit point source emissions that would be generated by the process unit operating at its maximum capacity.

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

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

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

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

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

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

(h) *Monitoring, recordkeeping and reporting.* (1) The permit shall set forth monitoring, recordkeeping, and reporting requirements sufficient to dem-

onstrate compliance with the site-wide emissions caps. The monitoring, recordkeeping and reporting requirements shall be structured in a tiered system, such that the requirements become more stringent as the site's emissions approach the total emissions cap.

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

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

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

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

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

(2) National ambient air quality standard or;

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

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

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

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(ii) If the permittee knowingly falsifies emissions data;

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

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

(v) If the total emissions cap is exceeded.

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

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

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

(i) Enter upon the site;

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

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

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

(v) Sample or monitor any substances or parameters at any location,

during operating hours, for the purpose of assuring permit compliance or as otherwise authorized by the Act.

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

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

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

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

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

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

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

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

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

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

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

(2) *Administrative permit modification.*

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

(A) Corrects typographical errors;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[62 FR 52638, Oct. 8, 1997]