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RE RACT Phase III for TVOP No. 46-00005
Merck, Sharp, and Dohme, LLC
APS No. 781343, AUTH No. 1421637
Upper Gwynedd Township
Montgomery County

Introduction

As part of the RACT regulations codified at 25 Pa. Code §§ 129.111—129.115 (relating to additional RACT requirements for major sources of NO_x and VOCs for the 2015 ozone NAAQS) (RACT III), PA DEP has established a method under 25 Pa. Code § 129.114(i) (relating to alternative RACT proposal and petition for alternative compliance schedule) for an applicant to demonstrate that the alternative RACT compliance requirements incorporated under 25 Pa. Code § 129.99 (relating to alternative RACT proposal and petition for alternative compliance schedule) (RACT II) that are currently in force in the applicable operating permit continue to be RACT under RACT III.

The procedures to demonstrate that RACT II equals RACT III are specified in 25 Pa. Code §§ 129.114(i)(1)(i), 129.114(i)(1)(ii) and 129.114(i)(2), that is, subsection (i), paragraphs (1) and (2). An applicant may submit an analysis, certified by the responsible official, that the RACT II permit requirements remain RACT for RACT III by following the procedures established under subsection (i), paragraphs (1) and (2).

Paragraph (1) establishes cost-effectiveness thresholds of \$7,500 per ton of NO_x emissions reduced and \$12,000 per ton of VOC emissions reduced as “screening level values” to determine the amount of analysis and due diligence that the applicant shall perform if there is no new pollutant specific air cleaning device, air pollution control technology or technique available at the time of submittal of the analysis. Paragraph (1) has two subparagraphs.

Subparagraph (i) under paragraph (1) specifies that the applicant that evaluates and determines that there is no new pollutant specific air cleaning device, air pollution control technology or technique available at the time of submittal of the analysis and that each technically feasible air cleaning device, air pollution control technology or technique evaluated for the alternative RACT requirement or RACT emission limitation approved by the Department (or appropriate approved local air pollution control agency) under 25 Pa. Code § 129.99(e) had a cost effectiveness equal to or greater than \$7,500 per ton of NO_x emissions reduced or \$12,000 per ton of VOC emissions reduced shall include the following information in the analysis:

- o A statement that explains how the owner or operator determined that there is no new pollutant specific air cleaning device, air pollution control technology or technique available.
- o A list of the technically feasible air cleaning devices, air pollution control technologies or techniques previously evaluated under RACT II.
- o A summary of the economic feasibility analysis performed for each technically feasible air cleaning device, air pollution control technology or technique in the previous bullet and the cost effectiveness of each technically feasible air cleaning device, air pollution control technology or technique as submitted previously under RACT II.
- o A statement that an evaluation of each economic feasibility analysis summarized in the previous bullet demonstrates that the cost effectiveness remains equal to or greater than \$7,500 per ton of NO_x emissions reduced or \$12,000 per ton of VOC emissions reduced.

Subparagraph (ii) under paragraph (1) specifies that the applicant that evaluates and determines that there is no new pollutant specific air cleaning device, air pollution control technology or technique available at the time of submittal of the analysis and that each technically feasible air cleaning device, air pollution control technology or technique evaluated for the alternative RACT requirement or RACT emission limitation approved by the Department (or appropriate approved local air pollution control agency) under 25 Pa. Code § 129.99(e) had a cost effectiveness less than \$7,500 per ton of NO_x emissions reduced or \$12,000 per ton of VOC emissions reduced shall include the following information in the analysis:

- o A statement that explains how the owner or operator determined that there is no new pollutant specific air cleaning device, air pollution control technology or technique available.
- o A list of the technically feasible air cleaning devices, air pollution control technologies or techniques previously evaluated under RACT II.
- o A summary of the economic feasibility analysis performed for each technically feasible air cleaning device, air pollution control technology or technique in the previous bullet and the cost effectiveness of each technically feasible air cleaning device, air pollution control technology or technique as submitted previously under RACT II.
- o A statement that an evaluation of each economic feasibility analysis summarized in the previous bullet demonstrates that the cost effectiveness remains less than \$7,500 per ton of NO_x emissions reduced or \$12,000 per ton of VOC emissions reduced.
- o A new economic feasibility analysis for each technically feasible air cleaning device, air pollution control technology or technique.

Paragraph (2) establishes the procedures that the applicant that evaluates and determines that there is a new or upgraded pollutant specific air cleaning device, air pollution control technology or technique available at the time of submittal of the analysis shall follow.

- o Perform a technical feasibility analysis and an economic feasibility analysis in accordance with 25 Pa. Code § 129.92(b) (relating to RACT proposal requirements).
- o Submit that analysis to the Department (or appropriate approved local air pollution control agency) for review and approval.

The applicant shall also provide additional information requested by the Department (or appropriate approved local air pollution control agency) that may be necessary for the evaluation of the analysis submitted under 25 Pa. Code § 129.114(i).

Facility Description

Merck, Sharp, and Dohme, LLC (“Merck”) is a research and development (R&D) and pharmaceutical manufacturing facility. The primary operations at the facility include biological operations, cleaning and disinfecting operations, and R&D. Ancillary or support operations include a powerhouse, which generates steam and electricity, and generators. The facility is located at 770 Sumneytown Pike, West Point, PA 19486. The facility is a major source for both nitrogen oxides (NO_x) and volatile organic compounds (VOC), and it operates under Title V Operating Permit (TVOP) No. 46-00005. The facility commenced operation prior to August 3, 2018; therefore, Merck is required to comply with the RACT regulations codified at 25 Pa. Code §§ 129.111-129.115 (RACT III). Merck submitted the Alternative RACT Compliance Analysis in accordance with 25 Pa. Code § 129.114(i) on December 23, 2022 as part of demonstrating compliance with RACT III.

Merck used the procedures in accordance with 25 Pa. Code § 129.114(i)(1)(i) to demonstrate that RACT II equals RACT III for the emission sources listed in Table 1. The procedures listed under 25 Pa. Code §§ 129.114(i)(1)(ii) and 129.114(i)(2) did not apply to any of the emission sources at Merck.

Table 1 – Emission Sources and Pollutant Evaluated Under 25 Pa. Code § 129.114(i)(1)(i)

Source ID	Source Name	Pollutant of Concern
033	Erie City Boiler 3	NOx – 98.0 TPY ¹ VOC – 2.72 TPY ²
035	Keeler Boiler 5	NOx – 82.0 TPY VOC – 2.18 TPY ²
105	Biological Manufacturing ³	VOC – 28.32 TPY
107	Building 12 ³	VOC – 30.6 TPY
108	Building 66 ³	VOC – 11.9 TPY
111	Building 62 ³	VOC – 7.08 TPY
N/A	Research and Development	VOC – 18.0 TPY ⁴

¹Tons per year (demonstrated on a 12-month rolling basis).

²For VOC, this source meets presumptive RACT under 25 Pa. Code § 129.112(d).

³Cleaning and disinfecting.

⁴Permit Limit.

Summary of RACT Requirements for Each Source

The redacted Significant Modification issued under Authorization ID 1154356 provides a simple format to review all the RACT II conditions. Refer to EPA Docket No. EPA-R03-OAR-2020-0597-0002 at <https://www.regulations.gov/> (Merck attachment, pages 644-666). Minor changes were made to several of the case-by-case sources:

- Minor changes were made to the Research and Development (R&D) requirements under Section C of the permit, where the list of buildings performing R&D has been revised to account for buildings that no longer perform R&D activities and buildings where R&D activities now take place. However, the VOC emission limit remains the same and the RACT analysis remains the same.
- For Source 105, the shell freezers were moved to a new Source ID 105A as the general requirements differed from the Biological Manufacturing operations. It was determined during the 2023 permit renewal for Title V Operating Permit No. 46-00005 that each shell freezer met presumptive RACT under 25 Pa. Code § 129.112(c)(2).
- For Source 107, the shell freezers were removed because they were also reflected under Source ID 380. It was determined during the 2023 permit renewal for Title V Operating Permit No. 46-00005 that each shell freezer under Source ID 380 met presumptive RACT under 25 Pa. Code § 129.112(c)(2).
- For Source 108, the shell freezers were removed because they were the same shell freezers that were reflected under Source ID 105, which are now reflected under Source ID 105A.

RACT II equals RACT III

The following subsections provide the analysis of alternative RACT compliance in accordance with 25 Pa. Code §129.114(i)(1)(i).

25 Pa. Code §129.114(i)(1)(i)(A)

Identification of New Air Cleaning Devices, Air Pollution Control Technologies, or Techniques

Merck reviewed entries in the RACT/BACT/LAER Clearinghouse (RBLC) to determine if any new technologies were applicable to the units onsite. No new technically feasible technologies were discovered and the work practices for the affected units are consistent with RBLC determinations.

25 Pa. Code §129.114(i)(1)(i)(B)

List Previously Identified Technically Feasible Controls

The previously identified technically feasible controls identified and evaluated under 25 Pa. Code §§ 129.92(b)(1)-(3) that were included in Merck's 25 Pa. Code §129.99(d) RACT submittal, previously approved by PADEP, were as follows:

Source 033: Erie City Boiler 3

Merck identified the following controls as technically feasible options:

- Good air pollution control practices
- Selective catalytic reduction
- Low-NOx burners
- Ultra low-NOx burners
- Flue gas recirculation

Source 035: Keeler Boiler

Merck identified the following controls as technically feasible options for the Keeler Boiler:

- Good air pollution control practices
- Selective catalytic reduction
- Low-NOx burners
- Ultra low-NOx burners
- Flue gas recirculation

Source IDs 105 (Biological Manufacturing), 107 (Building 12), 108 (Building 66), and 111 (Building 62)

Merck identified the following controls to be technically feasible for Biological Manufacturing operations covered under Source ID 105 and the Disinfecting Operations taking place in Buildings 12, 66, and 62:

- Good air pollution control practices
- Thermal and catalytic oxidation
- VOC concentrator with thermal oxidation
- Carbon adsorption
- Wet scrubber

Research and Development Activities

Merck identified good air pollution control practices as the only technically feasible control option for Research and Development Activities.

25 Pa. Code §129.114(i)(1)(i)(C)

Summary of Previous Economic Feasibility Analyses

Merck considered the control technologies of the above-mentioned options and summarized the results of the previous control cost analyses, which is outlined in Table 2.

Table 2 – Summary of Technically Feasible Control Options Considered for Economic Feasibility

Source	Technically Feasible Control Options	Economic Feasibility Cost Analysis Result
Source ID 033 Erie City Boiler 3	Good Air Pollution Control Practices	Already in Use
	Selective Catalytic Reduction (SCR)	Economically Infeasible (\$14,623/ton NOx removed)
	Low-NOx Burners	Already Installed
	Ultra Low-NOx Burners	Economically Infeasible (\$16,286/ton NOx removed)
	Flue Gas Recirculation (FGR)	Economically Infeasible (\$7,253/ton NOx removed)
Source ID 035 Keeler Boiler 5	Good Air Pollution Control Practices	Already In Use
	SCR	Economically Infeasible (\$9,435/ton NOx removed)
	Low-NOx Burners	Already Installed
	Ultra Low-NOx Burners	Economically Infeasible (\$9,563/ton NOx removed)
	FGR	Economically Infeasible (\$9,483/ton NOx removed)
Source ID 105 Biological Manufacturing Disinfecting Operations Source ID 107 Building 12 Source ID 108 Building 66 Source ID 111 Building 62	Good Air Pollution Control Practices	Already in Use
	Thermal Oxidization	Economically Infeasible (\$191,080/ton VOC removed)
	Catalytic Oxidization	Economically Infeasible (\$573,540/ton VOC removed)
	VOC Concentrator With Thermal Oxidation	Economically Infeasible (\$95,850/ton VOC removed)
	Carbon Adsorption	Economically Infeasible (\$532,580/ton VOC removed)
	Wet Scrubber	Economically Infeasible (\$469,180/ton VOC removed)
Research and Development Activities	Good Air Pollution Control Practices	Already in Use

25 Pa. Code §129.114(i)(1)(i)(D)
Statement of Economic Infeasibility

The summary of each economic feasibility analysis summarized in Table 2 demonstrates that the cost effectiveness remains equal to or greater than the amounts of \$7,500 per ton of NOx emissions reduced or \$12,000 per ton of VOC emissions reduced. The one exception is for the FGR control cost analysis for Erie City Boiler 3 (Source ID 033), which has been updated to reflect current prices in accordance with 25 Pa. Code §129.114(i)(1)(ii)(E). The updated control cost analysis for the Erie City Boiler 3 (Source ID 033) is reflected in Attachment B of the initial notification submitted by Merck (December 23, 2022).

RACT III Rule Compliance and Recordkeeping

In accordance with 25 Pa. Code §129.115(f), Merck will keep sufficient records for demonstrating compliance with the RACT III Rule, including continued compliance with the RACT-specific recordkeeping conditions of the current TVOP. In accordance with 25 Pa. Code §129.115(k), all records will be maintained for at least five years, and will be made available to PADEP upon receipt of a written request.

Summary of RACT requirement for each source:

Tables 3 and 4 summarize RACT III requirements for the RACT II = RACT III sources at the facility, including how they will comply with RACT. Source IDs 033 and 035 are subject to RACT for NOx. The other sources only emit VOC emissions.

Table 3 – RACT for NOx

Source ID	Source Name	RACT III requirements
033	Erie City Boiler 3	<p>Presumptive – 25 Pa. Code § 129.112(g): 0.10 lb NOx/MMBtu (natural gas), 0.12 lbs NOx/MMBtu (No. 2 fuel oil).</p> <p>Due to the age of the boiler, this boiler cannot meet presumptive RACT with the existing Low NOx Burners. RACT for this source is:</p> <ul style="list-style-type: none"> • Use of Low NOx Burners, biennial tune-ups (as per 40 CFR 63.11223), and 5-year NOx stack testing. • NOx emissions shall not exceed 0.15 lbs/MMBtu, on a daily basis (both fuels). • Fuel and hours of operation shall be monitored and recorded daily. • Compliance with the 0.15 lbs/MMBtu limit is determined by means of the 5-year NOx stack testing.
035	Keeler Boiler 5	<p>Presumptive – 25 Pa. Code § 129.112(g): 0.10 lbs NOx/MMBtu (natural gas), 0.12 lbs NOx/MMBtu (No. 2 fuel oil).</p> <p>Due to the age of the boiler, this boiler cannot meet presumptive RACT with the existing Low NOx Burners. RACT for this source is:</p> <ul style="list-style-type: none"> • Use of Low NOx Burners, biennial tune-ups (as per 40 CFR 63.11223), and 5-year NOx stack testing. • NOx emissions shall not exceed 0.20 lbs/MMBtu, on a daily basis (both fuels). • Fuel and hours of operation shall be monitored and recorded daily. • Compliance with the 0.20 lbs/MMBtu limit is determined by means of the 5-year NOx stack testing.

Table 4 – RACT for VOC

Source ID	Source Name	RACT III requirements
033	Erie City Boiler 3	This source meets presumptive RACT for VOC, under 25 Pa. Code § 129.112(d).
035	Keeler Boiler 5	This source meets presumptive RACT for VOC, under 25 Pa. Code § 129.112(d).
105 107 108 111	Biological Manufacturing Building 12 Building 66 Building 62	<p>These sources do not fall under any presumptive RACT category.</p> <p>These sources involve emissions of varying amounts of VOC occurring from aseptic disinfection procedures throughout operations occurring in various buildings. The primary issue is that the emissions do not occur in a common location such that they can be collected and vented to a control device in sufficient concentrations. RACT for these sources is:</p> <ul style="list-style-type: none"> • The permittee shall monitor and record solvent purchases (or solvent usage by means of mass balance) for disinfecting operations on a monthly basis and as a 12-month rolling sum. • The permittee shall maintain VOC emission factors and calculate VOC emissions on a monthly basis and as a 12-month rolling sum. • Work practice requirements include: 1) good housekeeping procedures for the storage, use, and disposal of solvents; 2) employee training detailing good work practices to control solvent usage for minimizing emissions; 3) periodic inspection of production and cleaning activities; and 4) solvent containers shall be closed when not in use. <p>The following emission limits apply per each Source ID:</p> <ul style="list-style-type: none"> • Source ID 105 – 28.32 tons of VOC per 12-consecutive month period. • Source ID 107 – 30.60 tons of VOC per 12-consecutive month period. • Source ID 108 – 11.90 tons of VOC per 12-consecutive month period. • Source ID 111 – 7.08 tons of VOC per 12-consecutive month period.
N/A	R&D (Section C)	<p>This source does not fall under any presumptive RACT category.</p> <p>This source involves emissions of varying amounts of VOC occurring from various Research and Development operations occurring throughout the site in various buildings. The primary issue is that the emissions do not occur in a common location such that they can be collected and vented to a control device in sufficient concentrations. RACT for these sources is:</p> <ul style="list-style-type: none"> • VOC emissions are limited to 18 tons per 12-rolling month period. • The permittee shall monitor and record the quantity of solvents used, along with the resulting VOC emissions, on a monthly basis and as a 12-month rolling sum. • Work practice requirements include: 1) operating and maintaining sources in accordance with good air pollution control practices; and 2) providing annual training in responsible environmental laboratory practices.

Public discussion

There have been no discussions that occurred with the EPA, the company, or the public after the company submitted the RACT II is RACT III proposal application.

Conclusion:

Pursuant to 25 Pa. Code § 129.114(j), DEP reviewed source information, control technologies, and measures evaluated by Merck, Sharp, and Dohme, LLC. The Department also performed an independent analysis, which included the Department's continuous review of permit applications since the applicability date of RACT II, internet searches, BACT/RACT/LAER Clearinghouse search, knowledge gained from the Department permitting staff participating in technical presentations by various vendors and manufacturers of pollution control technology, and a review of EPA and MARAMA's documents. Based on our review of these documents, along with training and the expertise of the reviewing staff, the Department concludes that there are no new or updated air pollution control technologies available for the sources found at Merck, Sharp, and Dohme, LLC. DEP has determined that RACT II requirements for those sources identified herein this technical review memo assure compliance with requirement for RACT III (25 Pa. Code §§ 129.111 - 129.115).

cc: TVOP No. 46-00005
Montgomery County District