



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R02-OAR-2024-0494; FRL 12517-01-R2]

### Air Plan Approval; New York; Ortho Clinical Diagnostics

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve a revision to the State of New York's State Implementation Plan (SIP) for the ozone National Ambient Air Quality Standard (NAAQS) related to a source-specific SIP (SSSIP) revision for Ortho Clinical Diagnostics, 513 Technology Boulevard, Rochester, New York (the Facility). The EPA is proposing to find that the control options in this SSSIP revision implement Reasonably Available Control Technology (RACT) with respect to volatile organic compound (VOC) emissions from the relevant Facility source, which are identified as one solvent-based film coating machine. This SSSIP revision is intended to implement VOC RACT for the relevant Facility source in accordance with the requirements for implementation of the 2008 and 2015 ozone NAAQS. EPA proposes to determine that this action will not interfere with ozone NAAQS requirements and meets all applicable requirements of the Clean Air Act (CAA).

**DATES:** Comments must be received on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA-R02-OAR-2024-0494 at <https://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Controlled Unclassified Information (CUI) (formerly referred to as Confidential Business Information (CBI)) or other information

whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be CUI or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CUI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** Linda Longo, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007-1866, (212) 637-3565, or by email at [longo.linda@epa.gov](mailto:longo.linda@epa.gov).

**SUPPLEMENTARY INFORMATION:** For additional information on regulatory background and the EPA's technical findings relating to the Facility RACT, the reader can refer to the Technical Support Document (TSD) that is contained in the EPA docket assigned to this *Federal Register* document.

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## **I. Background**

### *Ground level ozone formation*

Ground level ozone is predominantly a secondary air pollutant created by chemical reactions that occur when ozone precursors, including nitrogen oxides (NO<sub>x</sub>) and volatile organic compounds (VOC), chemically react in the presence of sunlight.<sup>1</sup> Emissions from industrial facilities are anthropogenic sources of ozone precursors. The potential for ground-level ozone formation tends to be highest during months with warmer temperatures and stagnant air masses. Ozone levels are thus generally higher during the summer months, which is often referred to as “the ozone season.” In New York, the ozone season is generally considered to be between April 15 and October 15, while the non-ozone season is generally considered to be between October 16 and April 14.

### *Ozone nonattainment*

A geographic area of the United States that is not meeting the primary or secondary National Ambient Air Quality Standard (NAAQS) for ozone is described as a nonattainment area. Nonattainment areas are classified as either Marginal, Moderate, Serious, Severe, or Extreme. With respect to this proposed action, there are two relevant ozone NAAQS standards. First, on March 12, 2008, the EPA promulgated a revision to the ozone NAAQS, setting both the primary and secondary standards at 0.075 parts per million (ppm) averaged over an 8-hour time frame (2008 8-hour Ozone Standard). *See* 73 FR 16436 (March 27, 2008). Second, on October 1, 2015, the EPA lowered these standards to 0.070 ppm averaged over an 8-hour time frame (2015 8-hour Ozone

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<sup>1</sup> *Primary standards* provide public health protection, including protecting the health of "sensitive" populations such as asthmatics, children, and the elderly. *Secondary standards* provide public welfare protection, including protection against decreased visibility and damage to animals, crops, vegetation, and buildings.

Standard). *See* 80 FR 65292 (October 26, 2015). Under CAA section 184, the State of New York is located within the Ozone Transport Region (OTR), which means that it is subject to statewide RACT requirements. This facility is not located in an ozone nonattainment area, but it is still required to implement RACT because it is located within the OTR.

#### *Federal RACT Requirements*

RACT is defined as the lowest emission limit that a source is capable of meeting through the application of control technology that is reasonably available considering technological and economic feasibility. CAA section 184(b)(2) sets forth the requirement to establish control measures to implement RACT for major sources of VOC located in the OTR. The State of New York is located within the OTR, and thus the State is required to implement RACT for all major sources of VOC within the State.

#### *NYSDEC RACT Requirements*

The New York State Department of Environmental Conservation (NYSDEC) RACT regulations require applicable facilities to meet certain requirements, referred to as “presumptive RACT requirements.” These presumptive requirements generally require sources to implement emission limits, control efficiency requirements, specific control technologies, averaging plans, and/or fuel/raw material switching practices. In some instances, the presumptive RACT requirements may not be technologically or economically feasible for a certain source, and the State can make a source-specific RACT determination, which is submitted to the EPA as a SSSIP. The SSSIP should include the facility’s RACT plan that demonstrates how the facility will implement RACT. The SSSIP will also include the applicable CAA operating permit conditions that address RACT requirements. These permit conditions for the Facility will become part of the Federally enforceable SIP upon the EPA’s final approval of this SSSIP.

Under existing NYSDEC RACT regulations, facilities are required to assess all technologically feasible control options that meet the State's cost threshold. The cost threshold for NYSDEC RACT requirements is found under NYSDEC 2013 policy, "DAR-20 Economic and Technical Analysis for Reasonably Available Control Technology (RACT)." Under this policy, facilities must consider in their RACT determinations control technologies that remove VOC or NOx emissions up to a certain cost threshold, expressed in a dollar amount per ton of VOC or NOx removed, which includes an inflation-adjusted economic threshold.<sup>2</sup>

## **II. The EPA's evaluation of New York's submission and RACT analysis**

This action relates to a SSSIP revision that concerns a web-based film coating machine for in-vitro diagnostics dry slide technology manufacturing operations. The source at issue in this action is for the Facility's pilot coating machine (the 72 Machine) for research and development of new potential products and material qualification experiments of non-compliant coatings. The 72 Machine also manufactures a small production run of equipment diagnostic calibration slides for internal purposes only. The 72 Machine is in total enclosure. The coating material is added to the process outside of the enclosed room and no workers are permitted to enter the enclosed room. To minimize VOC emissions, the overspray that can occur during coating operations is controlled using film manufacturing technology appropriate for the coating weight of the Ortho products. Generally, overspray can happen during a coating operation when the coating is applied onto a film substrate and if uncontrolled, overspray could generate excess VOC emissions. The 72 Machine's VOC exhaust is emitted via the roof vent.

The NYSDEC RACT regulations establish RACT requirements for this category of sources in 6 NYCRR part 228, "Surface Coating Processes, Commercial and Industrial

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<sup>2</sup> The DAR-20 cost threshold is based on 1994 dollars. State of New York relies on the U.S. Department of Labor, Bureau of Labor Statistics inflationary calculator to adjust the RACT economic feasibility threshold over time for inflation. See [https://www.bls.gov/data/inflation\\_calculator.htm](https://www.bls.gov/data/inflation_calculator.htm).

Adhesives Sealants and Primers”, subpart 228-1, “Surface Coating Processes”, subpart 228-1.5, “Requirements for Controlling VOC Emissions Using Add-On Controls or Coating Systems,” last approved into New York’s SIP by the EPA on March 4, 2014. *See* 79 FR 12082 (March 4, 2014). The coating machine meets the definition of a surface coating process under 6 NYCRR part 228-1 because it is a Class D coating line that applies solvent and aqueous based coatings to a polyethylene terephthalate substrate to produce testing slides.<sup>3</sup> However, as explained above, the NYSDEC RACT regulations allow source-specific RACT determinations if the presumptive RACT requirements are not technologically or economically feasible; such source-specific determinations must be submitted to the EPA as a SSSIP.

This SSSIP was submitted by NYSDEC on April 7, 2023. In this SSSIP submittal, the EPA has reviewed the RACT determination for 72 Machine for consistency with the CAA and the EPA regulations, as interpreted through EPA actions and guidance. The intended effect of this Source-specific SIP revision is to establish an emission limit for the process specific control measure for 72 Machine.

The EPA is proposing to determine through this SSSIP action that the VOC RACT emission limit submitted by the State in this SSSIP for 72 Machine is the lowest emission limit with the application of control technology that is reasonably available given technological and economic feasibility considerations. The respective VOC RACT emission limit is contained in the Facility’s air permit, State Facility Permit, 8-2628-00503/02001, under Condition 13, issued by the State on October 31, 2022, and expires on October 30, 2032. The Condition 13 is being incorporated into the SIP and includes monitoring, reporting, and recordkeeping requirements for the proposed coating machine referred to as 72 Machine further described in EPA RACT Analysis below.

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<sup>3</sup> 6 NYCRR part 228-1.1, Table 1, identifies the Class D coating line to include “paper”, “film”, and “foil” coating lines in the town of Monroe. The Facility produces “coil” that is similar to “foil.” Generally, coil is thicker than foil.

The Facility submitted a RACT demonstration, dated November 2021, to the NYSDEC for the emission limit requirements, and NYSDEC reviewed and approved the emission limit as adequately implementing RACT for the source. NYSDEC then submitted the source-specific SIP revision package at issue in this action for the EPA approval, and the EPA is proposing to determine the respective emission limit as implementing RACT for this source. The emission limit for the Facility will become part of the Federally enforceable SIP upon the EPA's final approval of this SSSIP.

*EPA RACT analysis*

The following is a summary of the EPA's analysis of how the proposed VOC emission limit implements RACT for the emission source 72 Machine. Further detail on this analysis is provided in the TSD available in the docket for this rulemaking. The Facility's coating machine, 72 Machine, is part of the coating line to produce testing slides. As described above, the 72 Machine is characterized as a surface coating process under subpart 228-1, "Surface Coating Processes".

The RACT demonstration must show an alternate emission limit to comprise RACT and a RACT variance can be requested pursuant to 6 NYCRR subpart 228-1.5(e). Such a RACT variance can be approved if supported by a RACT demonstration and submitted to the EPA for review as a SIP revision.

The Facility's RACT demonstration shows that controlling the overspray is the only VOC control technology that is technologically and economically feasible for this facility, and that controlling the overspray ensures the VOC emissions will not exceed 21,600 pounds per year on a 12-month rolling total basis. Under 6 NYCRR subpart 228-1.5(e), NYSDEC may allow surface coating processes to operate with a lesser degree of control, as established in the applicable presumptive RACT requirements, provided that a

process specific RACT demonstration satisfies NYSDEC's regulations, and it addresses technical and economic feasibility of utilizing compliant coatings.<sup>4</sup>

NYSDEC reviewed the RACT demonstration and determined that the alternate emission limit implements RACT for the 72 Machine. Specifically, NYSDEC approved the following case-by-case emission limit: (1) Aggregate VOC emissions from non-compliant coatings A1c, 49CKMB, 90WHT, 92BLK on 72 Machine must not exceed 21,600 pounds per year on a 12-month rolling total basis; (2) ensure that non-compliant coatings A1c, 49CKMB, 90WHT, 92BLK have the same specifications as described in the November 2021 RACT demonstration; (3) track usage monthly and report compliance status on an annual basis; (4) failure to meet the pounds per year limit established for this RACT variance shall be ground for termination of the RACT variance; (5) a RACT variance evaluation must be reassessed every five years; and (6) an updated RACT variance request must be submitted by the facility for any changes that will increase the emission rate of 72 Machine, including but not limited to changes to coating specification, coating machine operation parameters, or coating curing/drying time.

We are proposing to determine that the following additional technically feasible control options do not need to be implemented because they are not cost effective: (1) thermal oxidation; (2) catalytic oxidation; and (3) ducting the VOC exhaust from 72 Machine to the Facility's other coating machine (71 Machine<sup>5</sup>).

To determine what VOC control technologies could be economically and technologically feasible for the 72 Machine, the EPA reviewed the Reasonably Available

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<sup>4</sup> Under 6 NYCRR 228-1.5(c), "[t]he overall removal efficiency of an air cleaning device used as a control strategy must be determined, for every surface coating formulation, on a solids as applied basis using Equation 2 unless a 90 percent or greater overall removal efficiency is achieved by the air cleaning device. The air cleaning device must be designed and operated to provide, at a minimum, an overall removal efficiency of either 90 percent or as determined by Equation 2."

<sup>5</sup> The Facility operates a second coating machine, 71 Machine, that is not subject to this rulemaking because it currently employs a catalytic oxidizer with a heat exchanger and meets the presumptive VOC limits under permit Condition 36.

Control Technology/Best Available Control Technology/Lowest Achievable Emission Rate Clearinghouse (RBLC)<sup>6</sup> and the vendor quotes provided by the State as part of the RACT evaluation. The EPA's RBLC search criteria were based on the process type "Paper, Plastic, and Foil Web Surface Coating." The EPA's RBLC review reveals that there are three facilities in the United States that possibly operate with similar practices as 72 Machine: (1) Bemis Performance Packaging in Wisconsin manufactures flexible packing film and has a regenerative thermal oxidizer on a flexographic press machine; (2) American Packaging Corp in New York manufactures packaging material for the food industry and has a regenerative thermal oxidizer on a press machine; and (3) Bemis in Indiana is a polyethylene film plant and has a cyrel plate making process with a catalytic and regenerative thermal oxidizer. The EPA also reviewed four vendor quotes for the thermal and catalytic oxidizers as contained in the SSSIP submission, and they appear to be technically sound. A vendor quote was not provided for ducting the emissions from 72 Machine to 71 Machine because ducting is not a reliable option due to the following: (1) ducting would involve complicated planning for coating schedules, and the two machines would not be able to operate at the same time due to incompatible static pressure between both machines, and (2) ducting emissions from 72 Machine to 71 Machine would result in overall airflow to exceed the design capacity of the existing catalytic oxidizer on 71 Machine. The EPA confirms that no cost-effective VOC control technologies have become available that could be implemented on the Facility's 72 Machine. Further detail on RBLC results and cost effectiveness are provided in the TSD available in docket for this rulemaking.

The EPA is proposing to determine that the proposed limit for 72 Machine implements RACT because: (1) The 6 NYCRR part 228-1 presumptive VOC limit for

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<sup>6</sup> The RBLC contains case-specific information on the best available air pollution technologies that have been required to reduce the emission of air pollutants from stationary sources. *See* <https://cfpub.epa.gov/rblc/index.cfm?action=Search.BasicSearch&lang=en>.

Class D coating line (i.e., paper, film, and foil) of 0.08 pounds VOC per pound coating is not economically and technologically feasible for this source; (2) no additional control technologies beyond what are currently used at 72 Machine are technically and economically feasible; (3) emission limit of 21,600 pounds per year on a 12-month rolling total basis comprises RACT for this source; and (4) the SIP revision contains monitoring and reporting requirements.

### **III. Proposed Action**

The EPA is proposing to approve this source-specific revision because the limits included in the SSSIP implement RACT for 72 Machine. Based on information provided by NYSDEC, a thorough RBLC review of similar sources, and an analysis of this source-specific SIP revision, the EPA proposes to approve Ortho Clinical Diagnostics operation under the NYSDEC-approved VOC emission limit for the Facility's 72 Machine.

Specifically, the EPA proposes to determine the following SSSIP revision: (1) The aggregate VOC emissions from non-compliant coatings A1c, 49CKMB, 90WHT and 92BLK on 72 Machine must not exceed 21,600 pounds per year on a 12-month rolling total basis; (2) ensure that the non-compliant coatings have the same specifications as described in the RACT variance submitted November 2021; (3) track usage monthly and report compliance annually; (4) exceeding the 21,600 pounds per year limit shall be ground for termination of the RACT variance; (5) an updated RACT variance request must be submitted for any changes that will increase the emission rate, including but not limited to changes to coating specification, coating machine operation parameters, or coating curing/drying time; and (6) RACT must be reevaluated every 5 years and an updated RACT variance must be submitted every 5 years.

### **IV. Incorporation by Reference**

In this document, the EPA is proposing to include regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is

proposing to incorporate by reference revisions to Ortho Clinical Diagnostics State Facility Permit condition 13 as described in section II of this preamble. The EPA has made, and will continue to make, these materials generally available through [www.regulations.gov](http://www.regulations.gov).

## **V. Statutory and Executive Order Reviews**

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

#### **List of Subjects 40 CFR Part 52**

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compound.

(Authority: 42 U.S.C. 7401 *et seq.*)

**Michael Martucci,**

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*Region 2.*