250-RICR-120-05-26

TITLE 250 – DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

CHAPTER 120 – AIR RESOURCES

SUBCHAPTER 05 – AIR POLLUTION CONTROL

PART 26 – Control of Organic Solvent Emissions from Manufacturers of Synthesized Pharmaceutical Products

26.1 Purpose and Authority

26.1.1 Purpose

The purpose of this regulation is to limit volatile organic compound emissions from the manufacture of synthesized pharmaceutical products.

26.1.2 Authority

These regulations are authorized pursuant to R.I. Gen. Laws § 42-17.1-2(19) and R.I. Gen. Laws Chapter 23-23, and have been promulgated pursuant to the procedures set forth in the Rhode Island Administrative Procedures Act, R.I. Gen. Laws Chapter 42-35.

26.2 Application

The terms and provisions of this regulation shall be liberally construed to permit the Department to effectuate the purposes of state laws, goals and policies.

26.3 Severability

If any provision of this regulation or the application thereof to any person or circumstance, is held invalid by a court of competent jurisdiction, the validity of the remainder of the regulation shall not be affected thereby.

26.4 Incorporated Materials

A. These regulations hereby adopt and incorporate 40 C.F.R. §§ 60 Appendix A-1 Methods 1, 1A, 2, 2A, 2C, and 2D; 60 Appendix A-2 Methods 3 and 3A; 60 Appendix A-3 Method 4; 60 Appendix A-6 Method 18; 60 Appendix A-7 Methods 25 and 25A; (2018) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

B. These regulations hereby adopt and incorporate the American Society for Testing and Material's "Standard Test Method for Vapor Pressure-Temperature

Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope" (ASTM D2879-10) (2010) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

26.5 Definitions

A. Unless otherwise expressly defined in this section, the terms used in this regulation shall be defined by reference to Part 0 of this Subchapter (General Definitions). As used in this regulation, the following terms shall, where the context permits, be construed as follows:

1. "Condenser" means any device which cools a gas stream to a temperature which removes specific VOC by condensation.

2. "Control system" means any number of control devices, including condensers, which are designed and operated to reduce the quantity of VOC emitted to the atmosphere.

3. "Enclose" means to cover a volatile organic liquid surface in a manner such that it is not exposed to the atmosphere.

4. "Pharmaceutical product and intermediate" means any drug or chemical substance or any intermediate used to make a drug or chemical substance which is intended to be administered to a person or animal to prevent or cure disease or otherwise enhance physical or mental welfare.

5. "Production equipment exhaust system" means a device for collecting and directing out of the work area VOC fugitive emissions from reactor openings, centrifuge openings, and other vessel openings for the purpose of protecting workers from excessive VOC exposure.

6. "Reactor" means a vat or vessel, which may be jacketed to permit temperature control, designed to contain chemical reactions.

7. "Separation operation" means a physical or chemical process that separates a mixture of compounds and solvents into two (2) or more components. Specific mechanisms include but are not limited to: extraction, centrifugation, filtration, and crystallization.

8. "Synthesized pharmaceutical manufacturing" means manufacture of pharmaceutical products and intermediates by chemical synthesis. The production and recovery of materials produced via fermentation, extraction of organic chemicals from vegetative materials or animal tissues, and formulation and packaging of the product are not considered synthesized pharmaceutical manufacturing.

9. "Volatile organic compound" or "VOC" means "Volatile Organic Compound and Halogenated Organic Compound" or "VOC and HOC".

26.6 Applicability

A. This regulation applies to the following sources of volatile organic compounds (VOC) at all synthesized pharmaceutical manufacturing facilities:

1. Reactors;

2. Distillation operations;

3. Crystallizers;

4. Centrifuges;

5. Vacuum dryers;

6. Air dryers;

7. Production equipment exhaust systems;

8. Rotary vacuum filters and other filters;

9. Storage tanks;

10. In-process tanks; and

11. Leaks.

B. The owner or operator of a synthesized pharmaceutical manufacturing facility subject to this regulation shall control the VOC emissions from each vent which has the potential to emit fifteen (15) pounds per day (lb/day) (6.8 kilograms per day [kg/day]) or more of VOC from reactors, distillation operations, crystallizers, centrifuges, and vacuum dryers. VOC emissions shall be controlled in accordance with the requirements in § 26.7 of this Part.

C. An owner or operator of a facility which has sources whose emissions are below the threshold in § 26.6(B) of this Part shall comply with the certification, recordkeeping, and reporting requirements in §§ 26.10 and 26.11 of this Part for those sources.

D. Any facility or source that becomes or is currently subject to the provisions of this regulation by exceeding the applicability threshold in § 26.6(B) of this Part will remain subject to this regulation even if the emissions later fall below the applicability threshold.

26.7 Standards

A. Any source commencing operation after November 19, 1992 must meet the following emission limitations upon commencing operations:

1. Surface condensers or equivalent controls

a. If surface condensers are used, the condenser outlet gas temperature shall not exceed the allowable temperature limit described for each associated vapor pressure in the following table; or

Allowable condenser outlet gas temperature, EC	VOC vapor pressure at 20EC, kPa (psi)	
-25	>40.01	(5.8)
-15	>20.0	(2.9)
0	>10.0	(1.5)
10	>7.0	(1.0)
25	>3.5	(0.5)

b. If other controls such as carbon absorption or incineration are used, the VOC emissions shall be reduced by at least as much as they would be by using a surface condenser. All such controls must be approved by the Department.

2. Air dryers and production equipment exhaust systems

a. The owner or operator of a synthesized pharmaceutical manufacturing facility subject to this regulation shall reduce the VOC emissions from all air dryers and production equipment exhaust systems:

(1) By at least ninety percent (90%) on an hourly basis if actual emissions from all air dryers and production equipment exhaust are 150 kg/day (330 lb/day) or more of VOC, or

(2) To 15.0 kg/day (33 lb/day) or less if actual emissions from all air dryers and production equipment exhaust are less than 150 kg/day (330 lb/day) of VOC.

3. Storage Tanks

    a. The owner or operator of a synthesized pharmaceutical manufacturing facility subject to this regulation shall reduce the VOC emissions from storage tanks by:

        (1) Providing a vapor balance system or equivalent control that is at least ninety percent (90%) effective in reducing emissions from truck or railcar deliveries to storage tanks with capacities greater than 7,500 liters (L) (2,000 gallons [gal]) that store VOC with vapor pressures greater than 28.0 kiloPascals (kPa) (4.1 pounds per square inch [psi]) at 20 C (68°F); and

        (2) Installing pressure/vacuum conservation vents set at a minimum pressure of 0.2 kPa (0.03 pounds per square inch atmospheric [psia]) on all storage tanks that store VOC with vapor pressures greater than 10.0 kPa (1.5 psi) at 20°C (68°F).

4. Centrifuges, rotary vacuum filters, and other filters

    a. The owner or operator of a synthesized pharmaceutical facility subject to this regulation shall enclose all centrifuges, rotary vacuum filters, and other filters having an exposed liquid surface if the liquid contains VOC and exerts a total VOC vapor pressure of 3.50 kPa (0.5 psi) or more at 20°C (68°F), as determined by ASTM D2879-10, incorporated in § 26.4(B) of this Part.

5. In-process tanks

    a. The owner or operator of a synthesized pharmaceutical facility subject to this regulation shall install covers on all in-process tanks that contain VOC at any time. These covers shall be constructed of a nonporous or nonabsorbent material and form a tight seal with the sides of the tank and have no gaps or holes. These covers shall remain closed at all times except when production, sampling, maintenance, or inspection procedures require operator access.

6. Leaks

    a. The owner or operator of a synthesized pharmaceutical manufacturing facility subject to this regulation shall visually inspect for liquid leaks once per week and use a portable VOC detector to inspect for vapor leaks once per month to inspect all equipment listed in §§ 26.6(A)(1) through (11) of this Part. All leak repairs shall be completed as soon as practicable but no later than fifteen (15) calendar days after the leak is found.

26.8 Test Methods and Compliance Procedures

A. If a source uses air pollution control equipment to comply with the requirements of this regulation, compliance shall be demonstrated in accordance with 40 C.F.R. § 60, Appendix A, Method 18, Method 25, or Method 25A, incorporated in § 26.4(A) of this Part, or any other EPA approved method which has been approved by the Director.

B. Selection of a method for testing compliance shall be based on consideration of total concentration and speciation of the organics present and on consideration of the potential presence of interfering gases. Only Method 25, which measures VOC as carbon, may be used for determining destruction efficiency of incinerators or catalytic incinerators.

C. Except as indicated in §§ 26.8(C)(1) and (2) of this Part, a test shall consist of three (3) separate runs, each lasting a minimum of sixty (60) minutes, unless the Director determines that process variables dictate shorter sampling times.

1. When the test is being done to determine the efficiency of a fixed-bed carbon adsorption system with a common exhaust stack for all of the individual adsorber vessels, the test shall consist of three (3) separate runs, each coinciding with one or more complete sequences through the adsorption cycles of all the individual adsorber vessels.

2. When the test is being done to determine the efficiency of a fixed-bed carbon adsorption system with individual exhaust stacks for each adsorber vessel, each adsorber vessel shall be tested individually. The test for each adsorber vessel shall consist of three (3) separate runs. Each run shall coincide with one or more complete adsorption cycles.

D. Method 1 or 1A of 40 C.F.R. § 60 Appendix A-1, incorporated in § 26.4(A) of this Part, shall be used for velocity traverses.

E. Method 2, 2A, 2C, or 2D of 40 C.F.R. § 60 Appendix A-1, incorporated in § 26.4(A) of this Part, shall be used to measure velocity and volumetric flow rates.

F. Method 3 or 3A of 40 C.F.R. § 60 Appendix A-2, incorporated in § 26.4(A) of this Part, shall be used for O_2 and CO_2 analysis.

G. Method 4 of 40 C.F.R. § 60 Appendix A-3, incorporated in § 26.4(A) of this Part, shall be used to measure stack gas moisture.

H. Methods 2, 2A, 2C, 2D, 3, 3A and 4 of 40 C.F.R. § 60 Appendix A, incorporated in § 26.4(A) of this Part, shall be performed, as applicable, at least twice during each test run.

I. Use of modifications of any of the analytical methods specified in §§ 26.8(A) through (H) of this Part shall be approved or disapproved by the Director on a

case-by-case basis. An owner or operator shall submit sufficient documentation for the Director to find that the analytical methods specified in §§ 26.8(A) through (H) of this Part will yield inaccurate results and that the proposed modification is appropriate.

26.9 Monitoring for Air Pollution Control Equipment

A. At a minimum, continuous monitors measuring the following parameters shall be installed on air pollution control equipment used to control sources subject to this regulation upon startup:

1. Destruction device combustion temperature;

2. Temperature rise across a catalytic incinerator bed;

3. VOC concentration at the outlet of a carbon adsorption unit at breakthrough;

4. Outlet gas temperature of a refrigerated condenser; and

5. Outlet gas temperature of a non-refrigerated condenser coolant supply system.

B. Each monitor shall be:

1. Equipped with a recording device,

2. Calibrated quarterly, and

3. Operated at all times that the associated control equipment is operating.

26.10 Recordkeeping

A. The owner or operator of a pharmaceutical manufacturing facility subject to this shall maintain the following records:

1. Recording of parameters listed in § 26.9 of this Part.

2. A record of the solvent true vapor pressure as determined by ASTM D287910, incorporated in § 26.4(B) of this Part, for each VOC used in a source which is subject to this regulation. For a pure solvent, a record of published data reporting the true vapor pressure of that solvent as determined using ASTM D2879-10 is acceptable to fulfill this requirement.

B. For any leak subject to § 26.7(A)(6) of this Part, which cannot be readily repaired within twenty-four (24) hours after detection, the following shall be recorded:

1. The name of the leaking equipment;

2. The date and time the leak is detected;

3. The action taken to repair the leak; and

4. The date and time the leak is repaired.

C. All records required in this subsection shall be maintained at the facility for a minimum of five (5) years.

26.11Reporting

26.11.1 Initial Compliance Certification Plan

A. The owner or operator of any facility subject to this regulation shall submit an initial compliance certification for that source at least 6 months prior to start-up of the operation.

B. The initial compliance certification plan shall include as a minimum the following information:

1. The name and location of the facility;

2. The name, address and telephone number of the person responsible for the facility;

3. An identification of subject sources at the facility;

4. The information specified in § 26.11.1(C) of this Part for each subject source; and

5. The time at which the facility's "day" begins if a time other than midnight local time is used to define a "day".

C. The initial compliance certification plan shall also include, as a minimum, the following information for each subject source:

1. Identification of the applicable emission limitation, equipment specification, or work practice, as specified in § 26.7 of this Part;

2. The method by which compliance has been or will be achieved;

3. For each source subject to numerical emission limitations, the estimated actual and potential emissions without control, and the basis for the estimate.

26.11.2 Final Compliance Certification

A. Upon startup for a facility, the owner or operator of any facility containing sources subject to this regulation shall certify to the Director that the facility is in compliance with the provisions of this regulation.

B. The final compliance certification shall include, at a minimum, the following information:

1. The method by which compliance has been achieved for each subject source;

2. For each source subject to numerical emission limitations, the estimated actual and potential emissions without control, and the basis for the estimate;

3. Identification of the control system(s) in use for each subject source;

4. The design performance efficiency of the control system;

5. For each source subject to numerical emission limitations, the estimated emissions after control;

6. Certification that each subject source at the facility is in compliance with the applicable emission limitation, equipment specification, or work practice;

7. An identification of any changes from the initial compliance certification plan.

26.11.3 Reports of Noncompliance with Standards

A. The owner or operator of any facility containing sources subject to this section shall, for each incidence of noncompliance with the standards in § 26.7 of this Part, within thirty (30) calendar days of becoming aware of such occurrence, supply the Director with the following information:

1. The name and location of the facility;

2. The subject source(s) that caused the noncompliance with the standard;

3. The time and date of first observation of the incident of noncompliance;

4. The cause and expected duration of the incident of noncompliance;

5. For sources subject to numerical emission limitations, the estimated rate of emissions (expressed in the units of the applicable emission limitation) during the incident and the operating data and calculations used in estimating the emission rate.

6. The proposed corrective actions and schedule to correct the conditions causing the incidence of noncompliance.

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PART 26 - AIR POLLUTION CONTROL REGULATION NO. 26- CONTROL OF ORGANIC SOLVENT EMISSIONS FROM MANUFACTURERS OF SYNTHESIZED PHARMACEUTICAL PRODUCTS

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