10 CSR 10-5.350 Control of Emissions From Manufacture of Synthesized Pharmaceutical Products

(1) Application.

(A) This rule shall apply throughout St. Louis City, Jefferson, St. Charles, Franklin and St. Louis Counties.

(B) This rule applies to all synthesized pharmaceutical manufacturing installations.

(C) This rule applies only to operations including reactors, distillation units, dryers, storage of volatile organic compounds (VOC), transfer of volatile organic compounds, extraction equipment, filters, crystallizers and centrifuges that individually and uncontrolled would emit fifteen (15) pounds per day or more of volatile organic compounds.

(D) This rule does not apply to operations used exclusively for chemical or physical analysis or determination of product quality and commercial acceptance (such as research facilities, pilot plant operations, and laboratories) unless...

1. The operation is an integral part of the production process; or

2. The emissions from the operation exceed three hundred sixty-three (363) kg (800 pounds) in any calendar month.

(2) Definitions of certain terms specified in this rule may be found in 10 CSR 10-6.020.

(3) Operating Equipment and Operating Procedure Requirements.

(A) The owner or operator of a synthesized pharmaceutical manufacturing facility subject to this rule shall control the volatile organic compound emissions from all reactors, distillation operations, crystallizers, centrifuges and vacuum dryers by the use of surface condensers or equivalent control.

1. If surface condensers are used, the condenser outlet gas temperature must not exceed vapor pressures as measured at 20°C;

A. Minus twenty-five degrees Centigrade (-25°C), when condensing VOC of vapor pressure greater than 40.0 kPa (5.8 psi);

B. Minus fifteen degrees Centigrade (-15°C), when condensing VOC of vapor pressure greater than 20.0 kPa (2.9 psi);

C. Zero degrees Centigrade (0°C), when condensing VOC of vapor pressure greater than 10.0 kPa (1.5 psi);

D. Ten degrees Centigrade (10°C), when condensing VOC of vapor pressure greater than 7.0 kPa (1.0 psi); or

E. Twenty-five degrees Centigrade (25°C), when condensing VOC of vapor pressure greater than 3.50 kPa (0.5 psi).

2. If equivalent controls are used, the VOC emissions must be reduced by an amount equivalent to the reductions achieved in paragraph (3)(A)1. Equivalent controls may not be used unless approved by the director.

(B) The owner or operator of a synthesized pharmaceutical manufacturing installation subject to this rule shall reduce the VOC emissions from all air dryers and production equipment exhaust systems.

1. By at least ninety percent (90%) if emissions are one hundred fifty (150) kg/day (330 lb/day) or more of VOC; or

2. To 15.0 kg/day (33 lb/day) or less if emissions are less than one hundred fifty (150) kg/day (330 lb/day) of VOC.

(C) The owner or operator of a synthesized pharmaceutical manufacturing installation subject to this rule shall:

1. Provide a vapor recovery system or equivalent control that is ninety percent (90%) or more effective in reducing daily average emissions from truck or railcar deliveries to storage tanks with capacities greater than (7,500) liters (2,000 gallons) that store VOC with vapor pressures greater than 28.0 kPa (4.1 psi) at twenty degrees Celsius (20EC); and

2. Install pressure/vacuum conservation vents set at ± 0.2 kPa on all storage tanks that store VOC with vapor pressures greater than 10.0 kPa (1.5 psi) at twenty degrees Centigrade (20EC), unless a more effective control system is used.

(D) The owner or operator of a synthesized pharmaceutical manufacturing installation subject to this rule shall enclose all centrifuges, rotary vacuum filters, and other filters having an exposed liquid surface, where the liquid contains VOC and exerts a total VOC vapor pressure of 3.50 kPa (0.5 psi) or more at twenty degrees Centigrade (20°C).

(E) The owner or operator of a synthesized pharmaceutical manufacturing installation subject to this rule shall install covers on all in-process tanks containing a volatile organic compound at any time. These covers must remain closed, unless production, sampling, maintenance, or inspection procedures require operator access.

(F) The owner or operator of a synthesized pharmaceutical manufacturing installation subject to this rule shall repair all leaks from which a liquid, containing VOC, can be observed running or dripping. The repair shall be completed the first time the equipment is off-line for a period of time long enough to complete the repair.

(4) Compliance Determination and Recordkeeping.

(A) Compliance with this rule in subsections (3)(A), (3)(B) and paragraph (3)(C)1. shall be determined by the testing methods referenced in 10 CSR 10-6.030(14)(A).

(B) Owners or operators utilizing add-on control technology shall monitor and record the following parameters continuously while the affected equipment is in operation:

1. Exhaust gas temperature of all incinerators;

2. Temperature rise across a catalytic incinerator bed;

3. VOC breakthrough on a carbon adsorption unit;

4. Exit stream temperature on all condensers; and

5. Any other monitoring device requested by the director.

(C) Records shall be kept on production rates sufficient to determine daily VOC emissions and any equipment test results performed in conjunction with this rule.

(D) Records of all information requested in subsection (4)(B) shall be kept for a period of not less than two (2) years and all such records shall be made available to the director upon his/her request.

(5) Compliance Dates.

(A) The owner or operator of a synthesized pharmaceutical manufacturing installation subject to this rule must submit a final control plan to the director by December 31, 1980 for his approval. This plan must include the following:

1. A detailed plan of process modifications.

2. A time schedule for compliance containing increments of progress and a final compliance date.

(B) Compliance with this rule shall be accomplished by any installation as expeditiously as practicable, but in no case shall final compliance extend beyond December 31, 1982.

EPA Rulemakings

CFR: 40 C.F.R. 52.1320(c)(79)(i)(B)
FRM: 59 FR 43480 (8/24/94), Correction Notice 60 FR 16806 (4/3/95)
PRM: 57 FR 32191 (7/21/92)
State Submission: 11/20/91
State Proposal: 16 MR 989 (7/1/91)
State Final: 10 C.S.R. 10-5 (11/29/91)
APDB File: MO-100
Description: This revision updates this rule to included the correct reference method specified in 10 C.S.R. 10-6.030.

CFR: 40 C.F.R. 52.1320(c)(71)(i)(B)
FRM: 55 FR 7712 (3/5/90)
PRM: 54 FR 43183 (10/23/89)
State Submission: 3/30/89
State Proposal: 13 MR 1712 (10/17/88)
State Final: 14 MR 331 (3/1/89)
APDB File: MO-75
Description: The EPA approved a revision to the regulation which: (1) clarified applicability, (2) tightened recordkeeping requirements, (3) requires daily compliance, and (4) made other miscellaneous changes.

CFR: 40 C.F.R. 52.1320(c)(25)(vi)
FRM: 46 FR 20172 (4/3/81)
PRM: 45 FR 84099 (12/22/80)
State Submission: 9/2/80
State Proposal: 5 MR 382 (4/1/80)
State Final: 5 MR 1144 (9/2/80)
APDB File: MO-12
Description: The EPA approved a new regulation to control emissions from pharmaceutical manufacturing as part of the Set II VOC rules.

Difference Between the State and EPA-Approved Regulation

There is a minor difference in language in paragraph (3)(A)1.