

XIII.B.4. The overall reduction in VOC emissions specified in Subsection B.2 above shall be calculated by material balance methods approved by the Division, or by determination of capture and control device efficiencies. The overall VOC emission reduction rate equals the (percent capture efficiency X percent control device efficiency)/100.

XIII.C. Testing and Monitoring

The owner or operator of a source subject to the requirements of this section is also subject to the requirements of Section IX.A.3., IX.A.7., IX.A.9, and IX.A.10. In Section IX.A.3., EPA reference method 24A shall be the test method used for publication rotogravure inks, while EPA Reference method 24 data is acceptable for all other inks. Test methods as set forth in Appendix A, Part 60, Chapter I, Title 40, of the Code of Federal Regulations (CFR), in effect July 1, 1993.

XIII.D. The owner or operator of a source subject to the requirements of this section is also subject to the requirements of Section IX.A.8. "A Guideline for Graphic Arts Calculations" shall be used for compliance determination.

#### XIV. Pharmaceutical Synthesis

##### XIV.A. General Provisions

###### XIV.A.1. Applicability

This section applies to all sources of volatile organic compounds associated with pharmaceutical manufacturing activities, including, but not limited to, reactors, distillation units, dryers, storage of VOCs, extraction equipment, filters, crystallizers, and centrifuges.

###### XIV.A.2. Exemptions

Extraction of organic substances from animal or vegetable material; fermentation and culturing; formulation and packaging of pharmaceutical or medicinal products.

###### XIV.A.3. Definitions

For the purpose of this section, the following definitions apply:

XIV.A.3.a. "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.

XIV.A.3.b. "Pharmaceutical" means a medicine or drug which appears in the United States Pharmacopoeia National Formulary, or which is so designated by the National Drug Code of the United States FDA Bureau of Drugs.

XIV.A.3.c. "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.

XIV.A.3.d. "Reactor" means a vat or vessel, which may be jacketed to permit temperature control, designed to contain chemical reactions.

XIV.A.3.e. "Separation Operation" means a process that separates a mixture of compounds and solvents into two or more components. Specific mechanisms include, but are not limited to, extraction, centrifugation, filtration, distillation, and crystallization.

XIV.A.3.f. "Synthesized Pharmaceutical Manufacturing" means manufacture of pharmaceutical products by chemical synthesis. It includes the manufacture of chemical intermediates (of sufficient purity) which are typically used by the pharmaceutical industry as precursors to finished mixtures of chemicals. (Thus, it excludes those chemical processes which are not directed at creating finished pharmaceutical or chemical intermediates to finished pharmaceuticals.)

XIV.B. Provisions for Specific Processes

XIV.B.1. The owner or operator of a facility subject to this section shall control the volatile organic compound emissions from each vent which has the potential to emit 6.80 kg/day (15 lb./day) or more of VOC from reactors, distillation operations, crystallizers, centrifuge and vacuum dryers. Surface condensers or equivalent controls shall be used, provided that, if surface condensers are used, the condenser outlet gas temperature shall not exceed the following values:

| VOCs True Vapor Pressure* at 20° in torr (and psia) from (minimum) up to ** (maximum) | Maximum temperature of Gas Stream immediately exiting the condenser |
|---|---|
| 0-26(0-0.5)   | 35°C (95°F)   |
| 26-52(0.5-1.0)  | 25°C(77°F)  |
| 52-78(1.0-1.5)  | 10°C(50°F)  |
| 78-150(1.5-2.9)   | 0°C(32°F)   |
| 150-300(2.9-5.8)  | -15°C(5°F)  |
| Greater than 300(Greater than 5.8)  | -25°C(-13°F)  |

\*The calculation methods for gases containing more than one condensible component are complex. As a simplification, the temperature necessary for control by condensation can be roughly approximated by the weighted average of the temperatures necessary for condensation of each VOC considered separately but at concentrations equal to the total organic concentration.

\*\*But not including the maximum value of the range.

XIV.B.2. Division approval shall be required for control equipment used to control VOCs of 570 torr (11 psia) and above.

XIV.B.3. The owner or operator of a facility subject to this section shall reduce the VOC emissions from each air dryer and production equipment exhaust system:

XIV.B.3.a. By at least 90 percent if emissions are 150 kg/day (330 lbs/day) or more of VOC, or,

XIV.B.3.b. To 15.0 kg/day (33 lb/day) or less if emissions are less than 150 kg/day (330 lb/day) of VOC.

XIV.B.4. The owner or operator of a facility subject to this section shall:

XIV.B.4.a. Provide a vapor balance system or equivalent control that is at least 90.0 percent effective in reducing emissions from truck or railcar deliveries to storage tanks with capacities greater than 7,570 liters (2,000 gallons) that store VOC with true vapor pressure greater than 210 torr (4.1 psia) at 20°C, and,

XIV.B.4.b. Install pressure/vacuum conservation vents set at plus or minus 0.2 kPa on all storage tanks that store VOC with true vapor pressures greater than 10.0 kPa (1.5 psi) at 20°C.

XIV.B.5. The owner or operator of a facility subject to this section 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 true vapor pressure of 26 torr (0.5 psia) or more at 20°C.

XIV.B.6. The owner or operator of a synthesized pharmaceutical facility subject to this section shall install covers on all in-process tanks containing a volatile organic compound at any time. These covers shall remain closed unless sampling, maintenance, short-duration production procedures or inspection procedures require access.

XIV.B.7. The owner or operator of a facility subject to this section 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, except that no leak shall go unrepaired for more than 14 days after initial detection unless the Division issues written approval.

XIV.B.8. Each surface condenser shall have at least one temperature indicator with its sensor located in the outlet gas stream.

#### XIV.C. Testing and Monitoring

XIV.C.1. Sources subject to the requirements of this section are also subject to the requirements of Section 7.IX.A.3, IX.A.7., IX.A.8., and IX.A.9.

**XV. Control of Volatile Organic Compound Leaks from Vapor Collection Systems and Vapor Control Systems Located at Gasoline Terminals, Gasoline Bulk Plants, and Gasoline Dispensing Facilities**

XV.A. General Provisions

XV.A.1. Applicability

This section is applicable to all gasoline terminals, gasoline bulk plants and gasoline dispensing facilities (e.g., service stations) which are located in ozone nonattainment areas and which must have a vapor collection and/or a vapor control system pursuant to Section VI and other applicable rules.