

Title 26

DEPARTMENT OF THE ENVIRONMENT

Subtitle 11 AIR QUALITY

Chapter 19 Volatile Organic Compounds from Specific Processes

.14 Manufacture of Synthesized Pharmaceutical Products.

A. Definitions. In this regulation, the following terms have the meanings indicated:

(1) "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.

(2) "Synthesized pharmaceutical manufacturing" means manufacture of pharmaceutical products by chemical synthesis.

B. Emission Standards and Equipment Specifications.

(1) A person who owns or operates a synthesized pharmaceutical manufacturing facility shall control with surface condensers, or an equivalent control method approved by the Department, VOC emissions from any reactor, distillation operation, crystallizer, centrifuge, or vacuum dryer that has the potential to emit 15 pounds/day or more of VOC. The outlet gas temperature of a surface condenser may not exceed:

(a) Minus 13 deg. F when condensing VOC of vapor pressure greater than 5.8 psia at standard conditions;

(b) 5 deg. F when condensing VOC of vapor pressure greater than 2.9 psia at standard conditions;

(c) 32 deg. F when condensing VOC of vapor pressure greater than 1.5 psia at standard conditions;

(d) 50 deg. F when condensing VOC of vapor pressure greater than 1.0 psia at standard conditions;

(e) 77 deg. F when condensing VOC of vapor pressure greater than 0.5 psia at standard conditions.

(2) A person who owns or operates a synthesized pharmaceutical manufacturing facility may not cause or permit the discharge to the atmosphere of more than 33 pounds/day of

VOC from all air dryer and production equipment exhaust systems unless the discharge is reduced by 90 percent overall.

(3) A person who owns or operates a synthesized pharmaceutical manufacturing facility shall:

(a) Provide and use a vapor balance system or equivalent control that is at least 90 percent effective in reducing emissions from truck or railcar deliveries to any storage tank with a capacity greater than 2,000 gallons that stores VOC with vapor pressure greater than 1.5 psia at standard conditions; and

(b) Install and use pressure- or vacuum-conservation vents set at 0.05 psia (0.35 kilonewton/square meter), or an equivalent control method approved by the Department, on each storage tank that stores VOC with vapor pressure greater than 1.5 psia at standard conditions.

(4) A person who owns or operates a synthesized pharmaceutical manufacturing facility shall enclose each centrifuge, rotary vacuum filter, or other filter having an exposed liquid surface, where the liquid contains VOC and exerts a total VOC vapor pressure of 0.5 psia at standard conditions.

(5) A person who owns or operates a synthesized pharmaceutical manufacturing facility shall install covers on each in-process tank containing VOC at any time. These covers shall remain closed, except when production, sampling, maintenance, or inspection procedures require operator access.

(6) A person who owns or operates a synthesized pharmaceutical manufacturing facility shall repair as expeditiously as possible all leaks from which a liquid can be seen running or dripping.