

#### **401 KAR 59:230. New synthesized pharmaceutical product manufacturing operations.**

RELATES TO: KRS 224.20-100, 224.20-110, 224.20-120, 42 U.S.C. 7401 et seq., 7407, 7408, 7410

STATUTORY AUTHORITY: KRS 224.10-100

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 224.10-100 requires the Environmental and Public Protection Cabinet to prescribe administrative regulations for the prevention, abatement, and control of air pollution. 42 USC 7410 likewise requires the state to implement standards for national primary and secondary ambient air quality. This administrative regulation provides for the control of volatile organic compound emissions from new synthesized pharmaceutical product manufacturing operations.

Section 1. Definitions. As used in this administrative regulation, all terms not defined in this section shall have the meaning given to them in 401 KAR 59:001.

- (1) "Affected facility" means operations involved in the manufacture of pharmaceutical products by chemical synthesis, but does not include fermentation, extraction, or formulation and packaging.
- (2) "Extraction" means the manufacture of botanical and biological products by the extraction of organic chemicals from vegetative materials or animal tissues.
- (3) "Fermentation" means the production and separation of medicinal chemicals such as antibiotics and vitamins from microorganisms.
- (4) "Formulation and packaging" means the formulation of bulk pharmaceuticals into various dosage forms such as tablets, capsules, injectable solutions, ointments, etc., that can be taken by the patient immediately and in accurate amount.
- (5) "Classification date" means February 4, 1981.
- (6) "kPa" means kilopascals.
- (7) "psi" means pounds per square inch.

Section 2. Applicability.

- (1) This administrative regulation shall apply to:
  - (a) Each affected facility commenced on or after the classification date defined in Section 1 of this administrative regulation and located in a county or portion of a county designated as nonattainment for ozone in 401 KAR 51:010, for any classification except marginal; and
  - (b) Each affected facility commenced on or after June 24, 1992 which is part of a major source located in a county or portion of a county designated attainment or marginal nonattainment for ozone in 401 KAR 51:010.
- (2) Each affected facility commenced on or after the classification date defined in Section 1 of this administrative regulation but prior to June 24, 1992 which is part of a major source located in a county or portion of a county designated attainment or marginally nonattainment for ozone in 401 KAR 51:010 shall be exempt from this administrative regulation except that control devices and procedures required at the time it commenced shall continue to be operated and maintained.

Section 3. Standard for VOCs. The owner or operator of an affected facility to which this administrative regulation applies shall install, maintain and operate the control equipment and observe at all times the following operating requirements:

- (1)
  - (a) Each vent from reactors, distillation operations, crystallizers, centrifuges, and vacuum dryers that emit six and eight-tenths (6.8) kg/day (fifteen (15) lb/day) or more of VOCs shall be equipped with surface condensers or other methods of control which

provide emission reductions equivalent to the use of surface condensers which meet the requirements in paragraph (b) of this subsection.

(b) If surface condensers are used, the condenser outlet gas temperatures shall not exceed the following temperatures (degrees Celsius) if condensing VOCs with the respective minimum vapor pressures (kilopascals). All vapor pressures are measured to twenty (20) degrees Celsius.

1. Negative twenty-five (-25) °C; forty (40) kPa (five and eighteenths (5.8) psi);
2. Negative fifteen (-15) °C; twenty (20) kPa (two and nine-tenths (2.9) psi);
3. Zero °C; ten (10) kPa (one and five-tenths (1.5) psi);
4. Ten (10) °C; seven (7) kPa (one (1.0) psi); and
5. Twenty-five (25) °C; three and five-tenths (3.5) kPa (five-tenths (0.5) psi).

(2)

(a) For air dryers and production equipment exhaust systems that emit 150 kg/day (330 lbs/day) or more of VOCs, emissions shall be reduced ninety (90) percent.

(b) For air dryers and production equipment exhaust systems that emit less than 150 kg/day (330 lbs/day), emissions shall be reduced to fifteen (15) kg/day (thirty-three (33) lbs/day).

(3)

(a) For storage tanks storing VOCs with a vapor pressure greater than twenty-eight (28) kPa (four and one-tenth (4.1) psi) at twenty (20) °C, one (1) liter of displaced vapor shall be allowed to be released to the atmosphere for every ten (10) liters transferred (i.e., a ninety (90) percent effective vapor balance or equivalent) on truck or rail car delivery to all tanks greater than 7,500 liters (2,000 gal) capacity unless the tanks are equipped with floating roofs, vapor recovery systems, or their equivalent. This requirement does not apply to transfer of VOCs from one (1) in-plant location to another.

(b) For tanks storing VOCs with a vapor pressure greater than ten (10) kPa (one and five-tenths (1.5) psi) at twenty (20) °C, the pressure or vacuum conservation vents shall be set at plus or minus two-tenths (0.2) kPa, unless more effective air pollution control is used.

(4) All centrifuges containing VOCs, rotary vacuum filters processing liquid containing VOCs and other filters having an exposed liquid surface if the liquid contains VOCs shall be enclosed. This applies to liquids exerting a total VOCs vapor pressure of three and five-tenths (3.5) kPa (five-tenths (0.5) psi) or more at twenty (20) °C.

(5) All in-process tanks containing VOCs at any time shall have covers which shall be closed except for short periods when production, sampling, maintenance, or inspection procedures require operator access.

(6) For liquids containing VOCs, all leaks in which liquid is observed to be running or dripping from vessels and equipment (for example: pumps, valves, flanges) shall be repaired within fifteen (15) days. A visual recheck shall be made after repair. If the leak is still present or a new leak is created by the repair, further maintenance shall be performed until the VOC emission drops below the screening value (observed to be running or dripping). Leaks that cannot be repaired within fifteen (15) days shall be repaired during the next scheduled turnaround. If the cabinet requests it, the owner or operator shall demonstrate to the cabinet's satisfaction while the repairs could not be completed within the initial fifteen (15) day period. If the leak is unable to be brought into compliance, a variance shall be requested and obtained on an individual basis. Case-by-case alternatives approved by the cabinet, but not previously authorized by the U.S. EPA, shall be submitted to the U.S. EPA as a SIP revision. Leak detection or maintenance and repair procedures shall include maintaining a survey log identifying when the leak occurred and reporting every ninety (90) days those leaks not repaired after fifteen (15) days. The operator shall retain the survey log for two (2) years after the inspection is completed.

#### Section 4. Compliance Timetable.

- (1) Affected facilities which were subject to this administrative regulation as in effect on February 4, 1981, shall have achieved final compliance upon start-up.
- (2) The owner or operator of an affected facility that, on or after June 24, 1992, becomes subject to this administrative regulation for a reason other than construction, modification, or reconstruction shall be required to complete the following:
  - (a) Submit a final control plan for achieving compliance with this administrative regulation no later than three (3) months after the date the affected facility becomes subject to this administrative regulation.
  - (b) Award the control system contract no later than five (5) months after the date the affected facility becomes subject to this administrative regulation.
  - (c) Initiate on-site construction or installation of emissions control equipment no later than seven (7) months after the date the affected facility becomes subject to this administrative regulation.
  - (d) On-site construction or installation of emission control equipment shall be completed no later than eleven (11) months after the date the affected facility becomes subject to this administrative regulation.
  - (e) Final compliance shall be achieved no later than twelve (12) months after the date the affected facility becomes subject to this administrative regulation.
  - (f) If an affected facility becomes subject to this administrative regulation because it is located in a county previously designated nonurban nonattainment or redesignated in 401 KAR 51:010 after November 15, 1990, final compliance may be extended to May 31, 1995, and the schedule in paragraphs (a) through (d) of this subsection adjusted by the cabinet.

Section 5. Compliance Procedures. Compliance shall be determined based upon an engineering analysis by the cabinet of the control system design, control device efficiency, control system capture efficiency, and other factors that could influence the performance of the system. If requested by the cabinet, performance tests specified by the cabinet shall be conducted to determine the efficiency of the control device.

Section 6. Monitoring Requirements. If adsorbers, condensers, incinerators or scrubbers are used to achieve compliance with Section 3 of this administrative regulation, the following monitoring devices shall be an integral part of the control device:

- (1) For carbon adsorbers, a monitoring device connected to an alarm device, which indicates carbon bed breakthrough;
  - (2) For condensers, a temperature securing device located in the exit gas stream;
  - (3) For incinerators, temperature securing devices located in the combustion chamber for thermal incinerators and in the catalyst preheat chamber for catalytic incinerators; and
  - (4) For scrubbers, flow meters for measuring flow rate of scrubbing medium or pressure drop measuring devices indicating back pressure and pressure drop across the scrubber.
- (401 KAR 059:230. 7 Ky.R. 372; 543; eff. 2-4-1981; 18 Ky.R. 2635; 2947; 3351; eff. 6-24-1992; Crt eff. 11-21-2018; TAm eff. 2-14-2019; Crt. eff. 11-20-2025.)