

REGULATION 7.60 Standard of Performance for New Synthesized Pharmaceutical Product Manufacturing Operations

Air Pollution Control District of Jefferson County Jefferson County, Kentucky

Relates To: KRS Chapter 77 Air Pollution Control

Pursuant To: KRS Chapter 77 Air Pollution Control

Necessity and Function: KRS 77.180 provides that the Air Pollution Control Board may make and enforce all needful orders, rules, and regulations necessary or proper to accomplish the purposes of KRS Chapter 77. This regulation provides for the control of emissions from new pharmaceutical manufacturing operations.

SECTION 1 Applicability

This regulation applies to each affected facility commenced on or after May 20, 1981. Any source that is ever subject to this regulation will always be subject to it unless the source changes its process to one not covered by this regulation.

SECTION 2 Definitions

Terms used in this regulation not defined herein shall have the meaning given to them in Regulation 1.02.

- 2.1 "Affected facility" means all sources of VOC at any pharmaceutical manufacturing facility, including vents from reactors, distillation units, fryers, storage of VOC, transfer of VOC, extraction equipment, filters, crystallizers, and centrifuges that emit 6.8 kilograms (15 pounds) of VOC per day or more as determined by the CTG of Pharmaceutical Manufacture (EPA-450/2-78-029) Appendix B.
- 2.2 "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.
- 2.3 "Reactor" means a vat or vessel, which may be jacketed to permit temperature control, designed to contain chemical reactions.
- 2.4 "Separation operation" means a process that separates a mixture of compounds and solvents into two or more components. Specific mechanisms include extraction, centrifugation, filtration, and crystallization.
- 2.5 "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 vegetable materials or animal tissues, and formulation and packaging of the product is not covered by this regulation.

SECTION 3 Standard for Volatile Organic Compounds

The owner or operator of an affected facility shall install, maintain and operate the control equipment and observe at all times the following operating requirements:

- 3.1.1 Each vent from reactors, distillation operations, crystalizers, centrifuges, and vacuum dryers that emit 6.8 kg/day (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 section 3.1.2.
- 3.1.2 If surface condensers are used, the condenser outlet gas temperature shall not exceed the following temperatures (degrees Celsius) when condensing VOCs with the respective minimum vapor pressures (kilopascals). All vapor pressures are referenced to 20 °C:
- 3.1.2.1 Negative 25 °C; 40 kPa (5.8 psi);
 - 3.1.2.2 Negative 15 °C; 20 kPa (2.9 psi);
 - 3.1.2.3 0 °C; 10 kPa (1.5 psi);
 - 3.1.2.4 10 °C; 7 kPa (1.0 psi); and,
 - 3.1.2.5 25 °C; 3.5 kPa (0.5 psi).
- 3.2.1 For air dryers and production equipment exhaust systems that emit 150 kg/day (330 lb/day) or more of VOCs, emissions shall be reduced by 90%.
- 3.2.2 For air dryers and production equipment exhaust systems that emit less than 150 kg/day (330 lb/day), emissions shall be reduced to 15 kg/day (33 lb/day).
- 3.3.1 For storage tanks storing VOCs with a vapor pressure greater than 28 kPa (4.21 psi) at 20 °C, one liter of displaced vapor shall be allowed to be released to the atmosphere for every 10 liters transferred (i.e., a 90% effective vapor balance or equivalent) or truck/rail car delivery to all tanks greater than 7,500 liters (2,000 gal) capacity except where tanks are equipped with floating roofs, vapor recovery systems, or their equivalent. This requirement does not apply to transfer of VOCs from one in-plant location to another.
- 3.3.2 For tanks storing VOCs with a vapor pressure greater than 10 kPa (1.5 psi) at 20 °C, pressure/vacuum conservation vents shall be set at plus or minus 0.2 kPa, except where more effective air pollution control equipment is used.
- 3.4 All centrifuges containing VOCs, rotary vacuum filters processing liquid containing VOCs and any other filters having an exposed liquid surface where the liquid contains VOCs shall be enclosed. This applies to liquids exerting a total VOC vapor pressure of 3.5 kPa (0.5 psi) or more at 20 °C.
- 3.5 All in-process tanks containing VOC at any time shall have covers which shall be closed except for short periods when production, sampling, maintenance, or inspection procedures require operator access.
- 3.6 For liquids containing VOCs, all leaks in which liquid can be observed to be running or dripping from vessels and equipment (for example, pumps, valves, flanges) shall be repaired within 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 15 days shall be repaired during the next scheduled turnaround, or if unable to be brought into compliance a deviation shall be requested and obtained on an individual basis. Leak detection/ maintenance and repair procedures shall include maintaining a log identifying when the leak occurred and reporting every 90 days those leaks not repaired after 15 days. The operator shall retain the survey log for two years after the inspection is completed.

SECTION 4 Compliance Procedures

- 4.1 A new affected facility shall comply with this regulation on startup.

- 4.2 Compliance will be determined based upon an engineering analysis by the District of the control system design, control device efficiency, control system capture efficiency, and any other factors that could influence the performance of the system. If so requested by the District, performance tests as specified by the District shall be conducted in order to determine the efficiency of the control device.

SECTION 5 Monitoring Requirements

When absorbers, condensers, incinerators, or scrubbers are used to achieve compliance with Section 3, the following monitoring devices shall be an integral part of the control device:

- 5.1 For carbon absorbers, a monitoring device connected to an alarm device which indicates carbon bed breakthrough;
- 5.2 For condensers, a temperature sensing device located in the exit gas stream;
- 5.3 For incinerators, temperature sensing devices located in the combustion chamber for thermal incinerators and in the catalyst pre-heat chamber for catalytic incinerators; and
- 5.4 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.

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