**Section 218.480 Applicability**

a) The rules of this Subpart, except for Sections 218.483 through 218.485 of this Part, apply to all emission units of VOM, including but not limited to reactors, distillation units, dryers, storage tanks for VOL, equipment for the transfer of VOL, filters, crystallizers, washers, laboratory hoods, pharmaceutical coating operations, mixing operations and centrifuges used in manufacturing, including packaging, of pharmaceuticals, and emitting more than 6.8 kg/day (15 lbs/day) and more than 2,268 kg/year (2.5 tons/year) of VOM. If such an emission unit emits less than 2,268 kg/year (2.5 tons/year) of VOM, the requirements of this Subpart still apply to the emission unit if VOM emissions from the emission unit exceed 45.4 kg/day (100 lbs/day).

b) Notwithstanding subsection (a) of this Section, the air suspension coater/dryer, fluid bed dryers, tunnel dryers, and Accelacotas located in Libertyville Township, Lake County, Illinois shall be exempt from the rules of this Subpart, except for Sections 218.483 through 218.485, if emissions of VOM not vented to air pollution control equipment do not exceed the following levels:

1) For the air suspension coater/dryer: 2,268 kg/year (2.5 tons/year);

2) Except as set forth in subsection 218.480(b)(4) of this Section, for each fluid bed dryer: 4,535 kg/year (5.0 tons/year);

3) Except as set forth in subsection 218.480(b)(4) of this Section, for each tunnel dryer: 6,803 kg/year (7.5 tons/year);

4) For fluid bed dryers #1, #2, and #3 and for tunnel dryers #1, #2, #3, and #4, the combined total annual emissions from the dryers listed in this subsection 218.480(b)(4) shall not exceed 18,688 kg/year (20.6 tons/year).

[BOARD NOTE: tunnel dryers are otherwise referred to as warm air dryers]; and

5) For each Accelacota: 6,803 kg/year (7.5 tons/year).

c) Sections 218.483 through 218.485 of this Part apply to a source having one or more emission units that:

1) Are used to manufacture pharmaceuticals, and

2) Emit more than 6.8 kg/day (15 lbs/day) of VOM and more than 2,268 kg/year (2.5 tons/year) of VOM, or, if less than 2,268 kg/year (2.5 tons/year), these Sections still apply if emissions from one or more sources exceed 45.4 kg/day (100 lbs/day).

d) No owner or operator shall violate any condition in a permit when the condition results in exclusion of an emission unit from this Subpart.

e) Any pharmaceutical manufacturing source that becomes subject to the provisions of this Subpart at any time shall remain subject to the provisions of this Subpart at all times.

f) Emissions subject to this Subpart shall be controlled at all times consistent with the requirements set forth in this Subpart.

g) Any control device required pursuant to this Subpart shall be operated at all times when the source it is controlling is operated.

h) Determinations of daily and annual emissions for purposes of this Section shall be made using both data on the hourly emission rate (or the emissions per unit of throughput) and appropriate daily and annual data from records of emission unit operation (or material throughput or material consumption data). In the absence of representative test data pursuant to Section 218.487 of this Part for the hourly emission rate (or the emissions per unit of throughput) such items shall be calculated using engineering calculations, including the methods described in Appendix B of "Control of Volatile Organic Emissions from Manufacturing of Synthesized Pharmaceutical Products" (EPA-450/2-78-029), incorporated by reference in Section 218.112 of this Part. (This subsection shall not affect the Agency's or the USEPA's authority to require emission tests to be performed pursuant to Section 218.487 of this Part.)

i) Equipment and operations emitting VOM at a source subject to subsection (a) or (c) of this Section and used to produce pharmaceutical products or a pharmaceutical-like product such as a hormone, enzyme, or antibiotic, shall be deemed to be engaged in the manufacture of pharmaceuticals for the purposes of this Subpart.

(Source: Amended at 32 Ill. Reg. 14874, effective August 26, 2008)