**Section 219.480 Applicability**

a) The rules of this Subpart, except for Sections 219.483 through 219.485, 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 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) Sections 219.483 through 219.485 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 then 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).

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

d) 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.

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

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

g) 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 219.487 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 219.112 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 219.487 of this Part.)

h) 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 19 Ill. Reg. 6958, effective May 9, 1995)