
40 C.F.R. § 63.1250

Applicability.

(a) *Definition of affected source.* (1) The affected source subject to this subpart consists of the pharmaceutical manufacturing operations as defined in § 63.1251. Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations that meet the criteria specified in paragraphs (a)(1) (i) through (iii) of this section:

- (i) Manufacture a pharmaceutical product as defined in § 63.1251;
- (ii) Are located at a plant site that is a major source as defined in section 112(a) of the Act; and
- (iii) Process, use, or produce HAP.

(2) Determination of the applicability of this subpart shall be reported as part of an operating permit application or as otherwise specified by the permitting authority.

(b) *New source applicability.* A new affected source subject to this subpart and to which the requirements for new sources apply is: An affected source for which construction or reconstruction commenced after April 2, 1997, and the standard was applicable at the time of construction or reconstruction; or a pharmaceutical manufacturing process unit (PMPU) dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP for which construction commenced after April 2, 1997 or reconstruction commenced after October 21, 1999.

(c) *General provisions.* Table 1 of this subpart specifies and clarifies the provisions of subpart A of this part that apply to an owner or operator of an affected source subject to this subpart. The provisions of subpart A specified in Table 1 are the only provisions of subpart A that apply to an affected source subject to this subpart.

(d) *Processes exempted from the affected source.* The provisions of this subpart do not apply to research and development facilities.

(e) *Storage tank ownership determination.* The owner or operator shall follow the procedures specified in paragraphs (e)(1) through (5) of this section to determine to which PMPU a storage tank shall belong. If an owner or operator produces only pharmaceutical products, the procedures specified in paragraphs (e)(1) through (5) of this section are required only to determine applicability and demonstrate compliance with the pollution-prevention alternative specified in § 63.1252(e), or to determine new source applicability for a PMPU dedicated to manufacturing a single product as specified in paragraph (b) of this section.

(1) If a storage tank is dedicated to a single PMPU, the storage tank shall belong to that PMPU.

(2) If a storage tank is shared among process units (including at least one PMPU), then the storage tank shall belong to the process unit located on the same plant site as the storage tank that has the greatest annual

volume input into or output from the storage tank (i.e., said PMPU or process unit has the predominant use of the storage tank).

(3) If predominant use cannot be determined for a storage tank that is shared among process units (including at least one PMPU), then the owner or operator shall assign the storage tank to any one of the PMPU's that shares it and is also subject to this subpart.

(4) If the predominant use of a storage tank varies from year to year, then predominant use shall be determined based on the utilization that occurred during the year preceding September 21, 1998 for existing affected sources. For new affected sources, predominant use will be based on the first year after initial startup. The determination of predominant use shall be reported in the Notification of Compliance Status required by § 63.1260(f). If the predominant use changes, the redetermination of predominant use shall be reported in the next Periodic report.

(5) If the storage tank begins receiving material from (or sending material to) another PMPU, or ceases to receive material from (or send material to) a PMPU, or if the applicability of this subpart to a storage tank has been determined according to the provisions of paragraphs (e)(1) through (4) of this section and there is a significant change in the use of the storage tank that could reasonably change the predominant use, the owner or operator shall reevaluate the applicability of this subpart to the storage tank and report such changes to EPA in the next Periodic report.

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