

**Subpart GGG—National Emission Standards for Pharmaceuticals Production**

SOURCE: 63 FR 50326, Sept. 21, 1998, unless otherwise noted.

**§ 63.1250 Applicability.**

(a) *Definition of affected source.* The affected source subject to this subpart is the pharmaceutical manufacturing operation, 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) through (a)(3) of this section as follows:

(1) Manufacture a pharmaceutical product, as defined in § 63.1251;

(2) Are located at a plant site that is a major source as defined in section 112(a) of the Act; and

(3) Process, use, or produce HAP.

(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.

(c) *General Provisions.* Table 1 of this subpart specifies the provisions of subpart A of this part that apply to an owner or operator of an affected source subject to this subpart, and clarifies specific provisions in subpart A of this part as necessary for 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 (e)(5) of this section to determine to which PMPU a storage tank shall belong.

(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 PMPU's, then the storage tank shall belong to that PMPU 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 has the predominant use of the storage tank).

(3) If predominant use cannot be determined for a storage tank that is shared among PMPU's and if one of those PMPU's is subject to this subpart, the storage tank shall belong to said PMPU.

(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.

(f) *Compliance dates.* The compliance dates for affected sources are as follows:

(1) An owner or operator of an existing affected source must comply with the provisions of this subpart within 3 years after September 21, 1998.

(2) An owner or operator of a new or reconstructed affected source must comply with the provisions of this subpart on September 21, 1998 or upon startup, whichever is later.

(3) Notwithstanding the requirements of paragraphs (f)(1) and (2) of this section, a new source which commences construction or reconstruction after April 2, 1997 and before September 21, 1998 shall not be required to comply with such promulgated standard until 3 years after September 21, 1998 if:

(i) The promulgated standard is more stringent than the proposed standard; and

(ii) The owner or operator complies with the standard as proposed during the 3-year period immediately after September 21, 1998.

(4) Pursuant to section 112(i)(3)(B) of the Act, an owner or operator may request an extension allowing the existing source up to 1 additional year to comply with section 112(d) standards.

(i) For purposes of this subpart, a request for an extension shall be submitted no later than 120 days prior to the compliance dates specified in paragraphs (f)(1) through (3) of this section, except as provided in paragraph (f)(4)(ii) of this section. The dates specified in §63.6(i) for submittal of requests for extensions shall not apply to sources subject to this subpart.

(ii) An owner or operator may submit a compliance extension request after the date specified in paragraph (f)(4)(i) of this section provided the need for the compliance extension arose after that date and before the otherwise applicable compliance date, and the need arose due to circumstances beyond reasonable control of the owner or operator. This request shall include the data described in §63.6(i)(6)(i)(A), (B), (C), and (D).

(g) *Applicability of this subpart except during periods of startup, shutdown, and malfunction.* (1) Each provision set forth in this subpart shall apply at all times except that emission limitations shall not apply during periods of: startup; shutdown; and malfunction, if the startup, shutdown, and malfunction precludes the ability of a particular emission point of an affected source to comply with one or more specific emission limitations to which it is subject and the owner or operator follows the provisions for periods of startup, shutdown, and malfunction, as specified in §§63.1259(a)(3) and 63.1260(i). Startup,

shutdown, and malfunction are defined in §63.1251.

(2) The provisions set forth in §63.1255 of this subpart shall apply at all times except during periods of nonoperation of the PMPU (or specific portion thereof) in which the lines are drained and depressurized resulting in the cessation of the emissions to which §63.1255 of this subpart applies.

(3) The owner or operator shall not shut down items of equipment that are required or utilized for compliance with the emissions limitations of this subpart during times when emissions (or, where applicable, wastewater streams or residuals) are being routed to such items of equipment, if the shutdown would contravene emissions limitations of this subpart applicable to such items of equipment. This paragraph does not apply if the item of equipment is malfunctioning, or if the owner or operator must shut down the equipment to avoid damage due to a malfunction of the PMPU or portion thereof.

(4) During startups, shutdowns, and malfunctions when the emissions limitations of this subpart do not apply pursuant to paragraphs (g)(1) through (3) of this section, the owner or operator shall implement, to the extent reasonably available, measures to prevent or minimize excess emissions to the extent practical. For purposes of this paragraph, "excess emissions" means emissions in excess of those that would have occurred if there were no startup, shutdown, or malfunction and the owner or operator complied with the relevant provisions of this subpart. The measures to be taken shall be identified in the applicable startup, shutdown, and malfunction plan, and may include, but are not limited to, air pollution control technologies, work practices, pollution prevention, monitoring, and/or changes in the manner of operation of the source. Back-up control devices are not required, but may be used if available.

(h) *Consistency with other regulations.* (1) *Consistency with other MACT standards.* After the compliance dates specified in this section, an affected source subject to the provisions of this subpart that is also subject to the provisions of any other subpart of 40 CFR

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part 63 may elect, to the extent the subparts are consistent, which subpart under which to maintain records and report to EPA. The affected source shall identify in the Notification of Compliance Status report required by § 63.1260(f) under which authority such records will be maintained.

(2) *Consistency with 40 CFR parts 264 and 265, subparts AA, BB, and/or CC.* After the compliance dates specified in this section, if any affected source subject to this subpart is also subject to monitoring, recordkeeping, and reporting requirements in 40 CFR part 264, subpart AA, BB, or CC, or is subject to monitoring and recordkeeping requirements in 40 CFR part 265, subpart AA, BB, or CC and the owner or operator complies with the periodic reporting requirements under 40 CFR part 264, subpart AA, BB, or CC that would apply to the device if the facility had final-permitted status, the owner or operator may elect to comply either with the monitoring, recordkeeping, and reporting requirements of this subpart, or with the monitoring, recordkeeping, and reporting requirements in 40 CFR parts 264 and/or 265, as described in this paragraph, which shall constitute compliance with the monitoring, record keeping, and reporting requirements of this subpart. If the owner or operator elects to comply with the monitoring, recordkeeping, and reporting requirements in 40 CFR parts 264 and/or 265, the owner or operator shall report all information required by § 63.1260(g). The owner or operator shall identify in the Notification of Compliance Status required by § 63.1260(f) the monitoring, recordkeeping, and reporting authority under which the owner or operator will comply.

(3) *Consistency with 40 CFR 60.112b.* After the compliance dates specified in this section, a storage tank controlled with a floating roof and in compliance with the provisions of 40 CFR 60.112b, subpart Kb, constitutes compliance with the provisions of this subpart GGG. A storage tank with a fixed roof, closed vent system, and control device in compliance with the provisions of 40 CFR 60.112b, subpart Kb must comply with the monitoring, recordkeeping, and reporting provisions of this sub-

part GGG. The owner or operator shall identify in the Notification of Compliance Status report required by § 63.1260(f) which tanks are in compliance with subpart Kb.

(4) *Consistency with subpart I of this part.* After the compliance dates specified in this section, for equipment at an affected source subject to this subpart that is also subject to subpart I of this part, an owner or operator may elect to comply with either the provisions of this subpart GGG or the provisions of subpart I of this part. The owner or operator shall identify in the Notification of Compliance Status report required by § 63.1260(f) the provisions with which the owner elects to comply.

(5) *Consistency with other regulations for wastewater.* After the compliance dates specified in this section, the owner or operator of an affected wastewater that is also subject to provisions in 40 CFR parts 260 through 272 shall comply with the more stringent control requirements (e.g., waste management units, numerical treatment standards, etc.) and the more stringent testing, monitoring, recording, and recordkeeping requirements that overlap between the provisions of this subpart and the provisions of 40 CFR parts 260 through 272. The owner or operator shall keep a record of the information used to determine which requirements were the most stringent and shall submit this information if requested by the Administrator.

(i) For the purposes of establishing whether a person is in violation of this subpart, nothing in this subpart shall preclude the use of any credible evidence or information relevant to whether a source would have been in compliance with applicable requirements.

### § 63.1251 Definitions.

Terms used in this subpart are defined in the Act, in subpart A of this part, or in this section. If the same term is defined in subpart A of this part and in this section, it shall have the meaning given in this section for the purposes of this subpart.