6.4.2 *Oxygen Correction Factor*. Measured pollutant levels must be corrected for the amount of oxygen in the stack according to the following formula:

$$P_c = P_m \times 14/(E - Y)$$

Where:

P_c = concentration of the pollutant or standard corrected to 7 percent oxygen, dry basis;

P_m = measured concentration of the pollutant, dry basis;

E = volume fraction of oxygen in the combustion air fed into the device, on a dry basis (normally 21 percent or 0.21 if only air is fed);

Y = measured fraction of oxygen on a dry basis at the sampling point.

The oxygen correction factor is:

$$OCF = 14/(E - Y)$$

6.4.3 *Temperature Correction*. Correction values for temperature are obtainable from standard reference materials.

6.5 *Rolling Average*. A rolling average is the arithmetic average of all one-minute averages over the averaging period.

6.5.1 *One-Minute Average for CO and HHC CEMS*. One-minute averages are the arithmetic average of the four most recent 15-second observations and must be calculated using the following equation:

$$\bar{c} = \sum_{i=1}^{4} \frac{c_i}{4}$$

Where:

$\bar{c}$ = the one minute average

c_i = a fifteen-second observation from the CEM

Fifteen second observations must not be rounded or smoothed. Fifteen-second observations may be disregarded only as a result of a failure in the CEMS and allowed in the source's quality assurance plan at the time of the CEMS failure. One-minute averages must not be rounded, smoothed, or disregarded.

6.5.2 Ten Minute Rolling Average Equation. The ten minute rolling average must be calculated using the following equation:

$$C_{RA} = \sum_{i=1}^{10} \frac{\bar{c}_i}{10}$$

Where:

C_{RA} = The concentration of the standard, expressed as a rolling average

$\bar{c}_i$ = a one minute average

6.5.3 *Hourly Rolling Average Equation for CO and THC CEMS and Operating Parameter Limits*. The rolling average, based on a specific number integer of hours, must be calculated using the following equation:

$$C_{RA} = \sum_{i=1}^{60} \frac{\bar{c}_i}{60}$$

Where:

c_{RA} = The concentration of the standard, expressed as a rolling average

$\bar{c}_i$ = a one minute average

6.5.4 Averaging Periods for CEMS other than CO and THC. The averaging period for CEMS other than CO and THC CEMS must be calculated as a rolling average of all one-hour values over the averaging period. An hourly average is comprised of 4 measurements taken at equally spaced time intervals, or at most every 15 minutes. Fewer than 4 measurements might be available within an hour for reasons such as facility downtime or CEMS calibration. If at least two measurements (30 minutes of data) are available, an hourly average must be calculated. The *n*-hour rolling average is calculated by averaging the *n* most recent hourly averages.

6.6 Units of the Standards for the Purposes of Recording and Reporting Emissions. Emissions must be recorded and reported expressed after correcting for oxygen, temperature, and moisture. Emissions must be reported in metric, but may also be reported in the English system of units, at 7 percent oxygen, 20 °C, and on a dry basis.

6.7 Rounding and Significant Figures. Emissions must be rounded to two significant figures using ASTM procedure E–29–90 or its successor. Rounding must be avoided prior to rounding for the reported value.

7. Bibliography

1. 40 CFR part 60, appendix F, ''Quality Assurance Procedures: Procedure 1. Quality Assurance Requirements for Gas continuous Emission Monitoring Systems Used For Compliance Determination''.

[64 FR 53038, Sept. 30, 1999, as amended at 65 FR 42301, July 10, 2000]

Subpart FFF [Reserved]

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*. (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.

(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 no later than October 21, 2002.

(2) An owner or operator of a new or reconstructed affected source must comply with the provisions of this subpart on August 29, 2000 or upon startup, whichever is later.

(3) Notwithstanding the requirements of paragraph (f)(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 this subpart until September 21, 2001 if:

(i) The requirements of this subpart are more stringent than the requirements of this subpart in effect before August 29, 2000 and contained in the 40 CFR, part (63.1200–end), edition revised as of July 1, 2000; and

(ii) The owner or operator complies with the requirements published on April 2, 1997 (62 FR 15754) during the period until September 21, 2001.

(4) Notwithstanding the requirements of paragraph (f)(2) of this section, a new source which commences construction or reconstruction after September 21, 1998 and before April 10, 2000 shall not be required to comply with this subpart until October 21, 2002 if:

(i) The requirements of this subpart are more stringent than the requirements of this subpart in effect before August 29, 2000; and

(ii) The owner or operator complies with the requirements of this subpart in effect before August 29, 2000 during the period between startup and October 21, 2002.

(5) Notwithstanding the requirements of paragraph (f)(2) of this section, a new source which commences construction or reconstruction after April 10, 2000 and before August 29, 2000 shall not be required to comply with this subpart until August 29, 2001 if:

(i) The requirements of this subpart are more stringent than the requirements published on April 10, 2000 (65 FR 19152); and

(ii) The owner or operator complies with the requirements of this subpart in effect before August 29, 2000 during the period between startup and August 29, 2001.

(6) 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 (5) of this section, except as provided in paragraph (f)(6)(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)(6)(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) *Compliance with other MACT standards.* (i) 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 this part 63 may elect to comply with either the provisions of this subpart or the provisions of another applicable subpart governing the maintenance of records and reporting 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.

(ii) After the compliance dates specified in paragraph (f) of this section, at an offsite reloading or cleaning facility subject to §63.1253(f), compliance with the emission standards and associated initial compliance, monitoring, recordkeeping, and reporting provisions of any other subpart of this part 63 constitutes compliance with the provisions of §63.1253(f)(7) (ii) or (iii). The owner or operator of the affected storage tank shall identify in the Notification of Compliance Status report required by §63.1260(f) the subpart of this part 63 with which the owner or operator of the offsite reloading or cleaning facility complies.

(2) *Consistency with 40 CFR parts 264 and 265, subparts AA, BB, and/or CC.* (i) After the compliance dates specified in this section, if any control device 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, recordkeeping, 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) and (i). 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.

(ii) After the compliance dates specified in this section, if any equipment at an affected source that is subject to §63.1255, is also subject to 40 CFR part 264, subpart BB, or to 40 CFR part 265, subpart BB, then compliance with the recordkeeping and reporting requirements of 40 CFR parts 264 and/or 265

may be used to comply with the recordkeeping and reporting requirements of § 63.1255, to the extent that the requirements of 40 CFR parts 264 and/or 265 duplicate the requirements of § 63.1255. The owner or operator shall identify in the Notification of Compliance Status, required by § 63.1260(f), if the owner or operator will comply with the recordkeeping and reporting authority under 40 CFR parts 264 and/or 265.

(3) *Compliance with 40 CFR 60.112(b).* 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 subpart 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) *Compliance with subpart I of this part.* After the compliance dates specified in this section, an affected source with equipment subject to subpart I of this part may elect to comply with either the provisions of § 63.1255 or the provisions of subpart H of this part for all such equipment. 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) *Compliance with other regulations for wastewater.* After the compliance dates specified in this section, the owner or operator of an affected wastewater stream that is also subject to provisions in 40 CFR parts 260 through 272 may elect to determine whether this subpart or 40 CFR parts 260 through 272 contain the more stringent control requirements (*e.g.*, design, operation, and inspection requirements for waste management units; numerical treatment standards; etc.) and the more stringent testing, monitoring, recordkeeping, and reporting. Compliance with provisions of 40 CFR parts 260 through 272 that are determined to be more stringent than the requirements of this subpart constitutes compliance with this subpart. For example, provisions of 40 CFR parts 260 through 272 for treatment units that meet the conditions specified in § 63.1256(g)(13) constitute compliance with this subpart. In the Notification of Compliance Status report required by § 63.1260(f), the owner or operator shall identify the more stringent provisions of 40 CFR parts 260 through 272 with which the owner or operator will comply. The owner or operator shall also identify in the Notification of Compliance Status report required by § 63.1260(f) the information and procedures used to make any stringency determinations. If the owner or operator does not elect to determine the more stringent requirements, the owner or operator must comply with both the provisions of 40 CFR parts 260 through 272 and the provisions of this subpart.

(6) *Compliance with subpart PPP of this part.* After the compliance dates specified in this section, an affected source with equipment in a pharmaceutical manufacturing process unit that is also part of an affected source under subpart PPP of this part may elect to demonstrate compliance with § 63.1254 by controlling all process vents in accordance with § 63.1425 (b), (c)(1), (c)(3), (d), and/or (f). Alternatively, the owner or operator may elect to determine which process vents must be controlled to comply with the percent reduction requirements of § 63.1254 and control only those vents in accordance with § 63.1425 (b), (c)(1), (c)(3), (d), and/or (f). For any pharmaceutical manufacturing process unit controlled in accordance with the requirements of § 63.1425, the owner or operator must also comply with all other requirements in subpart PPP of this part. In the Notification of Compliance Status report required by § 63.1260(f), the owner or operator shall identify which pharmaceutical manufacturing process units are meeting the control requirements for process vents and all other requirements of subpart PPP of this part, and the owner or operator shall describe the calculations and other information used to identify which process vents must be controlled to comply with the percent reduction requirements of § 63.1254, if applicable.

(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 FR 50326, Sept. 21, 1998, as amended at 65 FR 52596, Aug. 29, 2000; 66 FR 40131, Aug. 2, 2001]

§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.

Active ingredient means any material that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. This term does not include food, food additives (except vitamins and other materials described by SIC code 2833 or 2834), color additives, cosmetics, in-vitro diagnostic substances, x-ray film, test indicator devices, and medical devices such as implants, artificial joints, surgical bandages, and stitching material.

Actual HAP emissions means the HAP emitted to the atmosphere from either uncontrolled or controlled emission points.

Air pollution control device or Control device means equipment installed on a process vent, storage tank, wastewater treatment exhaust stack, or combination thereof that reduces the mass of HAP emitted to the air. The equipment may consist of an individual device or a series of devices. Examples include, but are not limited to, incinerators, carbon adsorption units, condensers, flares, boilers, process heaters, and gas absorbers. Process condensers are not considered air pollution control devices or control devices.

Annual average concentration, as used in the wastewater provisions in §63.1256, means the total mass of partially soluble and/or soluble HAP compounds in a wastewater stream during the calendar year divided by the total mass of the wastewater stream discharged during the same calendar year, as determined according to the procedures specified in §63.1257(e)(1) (i) and (ii).

Automated monitoring and recording system means any means of measuring values of monitored parameters and creating a hard copy or computer record of the measured values that does not require manual reading of monitoring instruments and manual transcription of data values. Automated monitoring and recording systems include, but are not limited to, computerized systems and strip charts.

Batch emission episode means a discrete venting episode that may be associated with a single unit operation. A unit operation may have more than one batch emission episode. For example, a displacement of vapor resulting from the charging of a vessel with HAP will result in a discrete emission episode that will last through the duration of the charge and will have an average flowrate equal to the rate of the charge. If the vessel is then heated, there will also be another discrete emission episode resulting from the expulsion of expanded vapor. Both emission episodes may occur in the same vessel or unit operation. There are possibly other emission episodes that may occur from the vessel or other process equipment, depending on process operations.

Batch operation or Batch process means a noncontinuous operation involving intermittent or discontinuous feed into equipment, and, in general, involves the emptying of the equipment after the batch operation ceases and prior to beginning a new operation. Addition of raw material and withdrawal of product do not occur simultaneously in a batch operation.

Bench-scale batch process means a batch process (other than a research and development facility) that is capable of being located on a laboratory bench top. This bench-scale equipment will typically include reagent feed vessels, a small reactor and associated product separator, recovery and holding equipment. These processes are only capable of producing small quantities of product.