

been introduced into an air pollution control device to reduce the mass of HAP in the stream. If the process vent is not routed to an air pollution control device, uncontrolled emissions are those HAP emissions released to the atmosphere.

*Unit operation* means those processing steps that occur within distinct equipment that are used, among other things, to prepare reactants, facilitate reactions, separate and purify products, and recycle materials. Equipment used for these purposes includes but is not limited to reactors, distillation columns, extraction columns, absorbers, decanters, dryers, condensers, and filtration equipment.

*Vapor-mounted seal* means a continuous seal that completely covers the annular space between the wall of the storage tank or waste management unit and the edge of the floating roof and is mounted such that there is a vapor space between the stored liquid and the bottom of the seal.

*Volatile organic compounds (VOC)* means those materials defined in 40 CFR 51.100.

*Waste management unit* means the equipment, structure(s), and or devices used to convey, store, treat, or dispose of wastewater streams or residuals. Examples of waste management units include wastewater tanks, air flotation units, surface impoundments, containers, oil-water or organic-water separators, individual drain systems, biological wastewater treatment units, waste incinerators, and organic removal devices such as steam and air stripper units, and thin film evaporation units. If such equipment is used for recovery then it is part of a pharmaceutical process and is not a waste management unit.

*Wastewater* means any portion of an individual wastewater stream or any aggregation of wastewater streams.

*Wastewater stream* means water that is discarded from a PMPU through a single POD, that contains an annual average concentration of partially soluble and/or soluble HAP compounds of at least 5 parts per million by weight and a load of at least 0.05 kg/yr. The following are not considered wastewater streams for the purposes of this subpart:

- (1) Stormwater from segregated sewers;
- (2) Water from fire-fighting and deluge systems, including testing of such systems;
- (3) Spills;
- (4) Water from safety showers;
- (5) Samples of a size not greater than reasonably necessary for the method of analysis that is used;
- (6) Equipment leaks;
- (7) Wastewater drips from procedures such as disconnecting hoses after clearing lines; and
- (8) Noncontact cooling water.

*Wastewater tank* means a stationary waste management unit that is designed to contain an accumulation of wastewater or residuals and is constructed primarily of nonearthen materials (e.g., wood, concrete, steel, plastic) which provide structural support. Wastewater tanks used for flow equalization are included in this definition.

*Water seal controls* means a seal pot, p-leg trap, or other type of trap filled with water (e.g., flooded sewers that maintain water levels adequate to prevent air flow through the system) that creates a water barrier between the sewer line and the atmosphere. The water level of the seal must be maintained in the vertical leg of a drain in order to be considered a water seal.

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#### § 63.1252 Standards: General.

Each owner or operator of any affected source subject to the provisions of this subpart shall control HAP emissions to the level specified in this section on and after the compliance dates specified in § 63.1250(f). Initial compliance with the emission limits is demonstrated in accordance with the provisions of § 63.1257, and continuous compliance is demonstrated in accordance with the provisions of § 63.1258.

(a) *Opening of a safety device.* Opening of a safety device, as defined in § 63.1251, is allowed at any time conditions require it to do so to avoid unsafe conditions.

(b) *Closed-vent systems.* The owner or operator of a closed-vent system that contains bypass lines that could divert

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a vent stream away from a control device used to comply with the requirements in §§ 63.1253, 63.1254, and 63.1256 shall comply with the requirements of Table 4 to this subpart and paragraph (b)(1) or (2) of this section. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this paragraph.

(1) Install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in § 63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere; or

(2) Secure the bypass line valve in the closed position with a car seal or lock and key type configuration. A visual inspection of the seal or closure mechanism shall be performed at least once every month to ensure that the valve is maintained in the closed position and the vent stream is not diverted through the bypass line. Records shall be maintained as specified in § 63.1259(i)(6)(ii).

(c) *Heat exchange systems.* Except as provided in paragraph (c)(2) of this section, owners and operators of affected sources shall comply with the requirements in paragraph (c)(1) of this section for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations.

(1) The heat exchange system shall be treated according to the provisions of § 63.104, except that the monitoring frequency shall be no less than quarterly.

(2) For identifying leaking equipment, the owner or operator of heat exchange systems on equipment which meet current good manufacturing practice (CGMP) requirements of 21 CFR part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system leaks around the reactor.

(d) *Emissions averaging provisions.* Except as specified in paragraphs (d)(1) through (5) of this section, owners or operators of storage tanks or processes subject to the provisions of §§ 63.1253

and 63.1254 may choose to comply by using emissions averaging requirements specified in § 63.1257(g) or (h) for any storage tank or process.

(1) A State may prohibit averaging of HAP emissions and require the owner or operator of an existing source to comply with the provisions in §§ 63.1253 and 63.1254.

(2) Only emission sources subject to the requirements of § 63.1253(b)(1) or (c)(1)(i) or § 63.1254(a)(1)(i) may be included in any averaging group.

(3) Processes which have been permanently shutdown or storage tanks permanently taken out of HAP service may not be included in any averaging group.

(4) Processes and storage tanks already controlled on or before November 15, 1990 may not be included in an emissions averaging group, except where the level of control is increased after November 15, 1990. In these cases, the uncontrolled emissions shall be the controlled emissions as calculated on November 15, 1990 for the purpose of determining the uncontrolled emissions as specified in § 63.1257(g) and (h).

(5) Emission points controlled to comply with a State or Federal rule other than this subpart may not be credited in an emission averaging group, unless the level of control has been increased after November 15, 1990 above what is required by the other State or Federal rule. Only the control above what is required by the other State or Federal rule will be credited. However, if an emission point has been used to generate emissions averaging credit in an approved emissions average, and the point is subsequently made subject to a State or Federal rule other than this subpart, the point can continue to generate emissions averaging credit for the purpose of complying with the previously approved average.

(6) Not more than 20 processes subject to § 63.1254(a)(1)(i), and 20 storage tanks subject to § 63.1253(b)(1) or (c)(1)(i) at an affected source may be included in an emissions averaging group.

(7) Compliance with the emission standards in § 63.1253 shall be satisfied when the annual percent reduction efficiency is greater than or equal to 90

percent for those tanks meeting the criteria of § 63.1253(a)(1) and 95 percent for those tanks meeting the criteria of § 63.1253(a)(2), as demonstrated using the test methods and compliance procedures specified in § 63.1257(g).

(8) Compliance with the emission standards in § 63.1254(a)(1)(i) shall be satisfied when the annual percent reduction efficiency is greater than or equal to 93 percent, as demonstrated using the test methods and compliance procedures specified in § 63.1257(h).

(e) *Pollution prevention alternative.* Except as provided in paragraph (e)(1) of this section, an owner or operator may choose to meet the pollution prevention alternative requirement specified in either paragraph (e)(2) or (3) of this section for any PMPU or for any situation described in paragraph (e)(4) of this section, in lieu of the requirements specified in §§ 63.1253, 63.1254, 63.1255, and 63.1256. Compliance with paragraphs (e)(2) and (3) of this section shall be demonstrated through the procedures in § 63.1257(f). Any PMPU for which the owner or operator seeks to comply by using the pollution prevention alternative shall begin with the same starting material(s) and end with the same product(s). The owner or operator may not comply with the pollution prevention alternative by eliminating any steps of a process by transferring the step offsite (to another manufacturing location).

(1) The HAP that are generated in the PMPU that are not part of the production-indexed consumption factor must be controlled according to the requirements of §§ 63.1253, 63.1254, 63.1255, and 63.1256. The hydrogen halides that are generated as a result of combustion control of emissions must be controlled according to the requirements of paragraph (g)(1) of this section.

(2) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by at least 75 percent from a 3 year average baseline established no earlier than the 1987 calendar year, or for the time period from startup of the process until the present in which the PMPU was operational and data are available, whichever is the lesser time period. If a time period less than 3 years is used to set the baseline, the data must represent

at least 1 year's worth of data. For any reduction in the HAP factor achieved by reducing a HAP that is also a VOC, an equivalent reduction in the VOC factor is also required. For any reduction in the HAP factor that is achieved by reducing a HAP that is not a VOC, the VOC factor may not be increased.

(3) Both requirements specified in paragraphs (e)(3)(i) and (ii) of this section are met.

(i) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by at least 50 percent from a 3-year average baseline established no earlier than the 1987 calendar year, or for the time period from startup of the process until the present in which the PMPU was operational and data are available, whichever is less. If a time period less than 3 years is used to set the baseline, the data must represent at least 1 year's worth of data. For any reduction in the HAP factor achieved by reducing a HAP that is also a VOC, an equivalent reduction in the VOC factor is also required. For any reduction in the HAP factor that is achieved by reducing a HAP that is not a VOC, the VOC factor may not be increased.

(ii) The total PMPU HAP emissions shall be reduced by an amount, in kg/yr, that, when divided by the annual production rate, in kg/yr, and added to the reduction of the production-indexed HAP consumption factor, in kg/kg, yields a value of at least 75 percent of the average baseline HAP production-indexed consumption factor established according to paragraph (e)(3)(i) of this section according to the equation provided in § 63.1257(f)(2)(ii)(A). The total PMPU VOC emissions shall be reduced by an amount calculated according to the equation provided in § 63.1257(f)(2)(ii)(B). The annual reduction in HAP and VOC air emissions must be due to the use of the following control devices:

(A) Combustion control devices such as incinerators, flares or process heaters.

(B) Control devices such as condensers and carbon adsorbers whose recovered product is destroyed or shipped offsite for destruction.

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(C) Any control device that does not ultimately allow for recycling of material back to the PMPU.

(D) Any control device for which the owner or operator can demonstrate that the use of the device in controlling HAP emissions will have no effect on the production-indexed consumption factor for the PMPU.

(4) The owner or operator may comply with the requirements in either paragraph (e)(2) or (3) of this section for a series of processes, including situations where multiple processes are merged, subject to the following conditions:

(i) The baseline period shall be a single year beginning no earlier than the 1992 calendar year.

(ii) The term "PMPU" shall have the meaning provided in §63.1251 except that the baseline and modified PMPU may include multiple processes (*i.e.*, precursors, active ingredients, and final dosage form) if the owner or operator demonstrates to the satisfaction of the Administrator that the multiple processes were merged after the baseline period into an existing process or processes.

(iii) Nondedicated formulation and solvent recovery processes may not be merged with any other processes.

(f) *Control requirements for certain liquid streams in open systems within a PMPU.* (1) The owner or operator shall comply with the provisions of Table 5 of this subpart, for each item of equipment meeting all the criteria specified in paragraphs (f)(2) through (4) and either paragraph (f)(5)(i) or (ii) of this section.

(2) The item of equipment is of a type identified in Table 5 of this subpart;

(3) The item of equipment is part of a PMPU, as defined in §63.1251;

(4) The item of equipment is controlled less stringently than in Table 5 of this subpart and the item of equipment is not otherwise exempt from controls by the provisions of this subpart or subpart A of this part; and

(5) The item of equipment:

(i) Is a drain, drain hub, manhole, lift station, trench, pipe, or oil/water separator that conveys water with an annual average concentration greater than or equal to 1,300 parts per million by weight (ppmw) of partially soluble

HAP compounds; or an annual average concentration greater than or equal to 5,200 ppmw of partially soluble and/or soluble HAP compounds. The annual average concentration shall be determined according to the procedures in §63.1257(e)(1)(ii).

(ii) Is a tank that receives one or more streams that contain water with an annual average concentration greater than or equal to 1,300 ppmw of partially soluble HAP compounds, or greater than or equal to 5,200 ppmw of total partially soluble and/or soluble HAP compounds. The owner or operator of the source shall determine the average concentration of the stream at the inlet to the tank and according to the procedures in §63.1257(e)(1)(ii).

(g) *Control requirements for halogenated vent streams that are controlled by combustion devices.* If a combustion device is used to comply with the provisions of §§63.1253 (storage tanks), 63.1254 (process vents), 63.1256(h) (wastewater vent streams) for a halogenated vent stream, then the vent stream shall be ducted to a halogen reduction device such as, but not limited to, a scrubber, before it is discharged to the atmosphere. The halogen reduction device must reduce emissions by the amounts specified in either paragraph (g)(1) or (2) of this section.

(1) A halogen reduction device after the combustion control device must reduce overall emissions of hydrogen halides and halogens, as defined in §63.1251, by 95 percent or to a concentration less than or equal to 20 ppmv.

(2) A halogen reduction device located before the combustion control device must reduce the halogen atom content of the vent stream to a concentration less than or equal to 20 ppmv.

(h) *Planned routine maintenance for centralized combustion control devices.* The owner or operator may operate non-dedicated PMPU's during periods of planned routine maintenance for CCCD in accordance with the provisions specified in paragraphs (h)(1) through (6) of this section.

(1) For equipment leaks and wastewater emissions that normally are controlled by the CCCD, if any, the owner or operator must continue to comply

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with the requirements in §§ 63.1255(b)(4)(ii) and 63.1256(h), respectively, using other control devices during the planned routine maintenance period for the CCCD.

(2) During the planned routine maintenance period, the owner or operator must route emissions from process vents with organic HAP emissions greater than 15 pounds per day (lb/day) through a closed-vent system to a condenser that meets the conditions specified in paragraphs (h)(2)(i) through (iii) of this section.

(i) The outlet gas temperature must be less than  $-50\text{ }^{\circ}\text{C}$  ( $-58\text{ }^{\circ}\text{F}$ ) when the emission stream contains organic HAP with a partial pressure greater than 20 kPa (2.9 psia).

(ii) The outlet gas temperature must be less than  $-5\text{ }^{\circ}\text{C}$  ( $23\text{ }^{\circ}\text{F}$ ) when the emission stream contains organic HAP with a partial pressure less than or equal to 20 kPa (2.9 psia).

(iii) The HAP partial pressures in paragraphs (h)(2)(i) and (ii) of this section must be determined at  $25\text{ }^{\circ}\text{C}$ .

(3) The owner or operator must route HCl emissions from process vents with HCl emissions greater than 15 lb/day through a closed-vent system to a caustic scrubber, and the pH of the scrubber effluent must be maintained at or above 9.

(4) For the purposes of the emission calculations required in paragraphs (h)(2) and (3) of this section, the term "process vent" shall mean each vent from a unit operation. The emission calculation shall not be performed on the aggregated emission stream from multiple unit operations that are manifolded together into a common header. Once an affected process vent has been controlled in accordance with this section, it is no longer subject to the requirements of this section or § 63.1254 during the routine maintenance period.

(5) The total period of planned routine maintenance, during which non-dedicated PMPUs that are normally controlled by the CCCD continue to operate, and process vent emissions are controlled as specified in paragraphs (h)(2) and (3) of this section, must not exceed 240 hours in any 365-day period.

(6) While being controlled as specified in paragraphs (h)(2) and (3) of this section,

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tion, the process vents may not be used in emissions averaging.

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#### § 63.1253 Standards: Storage tanks.

(a) Except as provided in paragraphs (d), (e), and (f) of this section, the owner or operator of a storage tank meeting the criteria of paragraph (a)(1) of this section is subject to the requirements of paragraph (b) of this section. Except as provided in paragraphs (d), (e), and (f) of this section, the owner or operator of a storage tank meeting the criteria of paragraph (a)(2) of this section is subject to the requirements of paragraph (c) of this section. Compliance with the provisions of paragraphs (b) and (c) of this section is demonstrated using the initial compliance procedures in § 63.1257(c) and the monitoring requirements in § 63.1258.

(1) A storage tank with a design capacity greater than or equal to  $38\text{ m}^3$  but less than  $75\text{ m}^3$  storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa.

(2) A storage tank with a design capacity greater than or equal to  $75\text{ m}^3$  storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa.

(b) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of § 63.1252(b) with a control device that meets any of the following conditions:

(1) Reduces inlet emissions of total HAP by 90 percent by weight or greater;

(2) Reduces emissions to outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;

(3) Is an enclosed combustion device that provides a minimum residence time of 0.5 seconds at a minimum temperature of  $760\text{ }^{\circ}\text{C}$ ;

(4) Is a flare that meets the requirements of § 63.11(b); or