

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.

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§ 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.

Block means a time period that comprises a single batch.

Boiler means any enclosed combustion device that extracts useful energy in the form of steam and is not an incinerator. Boiler also means any industrial furnace as defined in 40 CFR 260.10.

Centralized combustion control device (CCCD) means enclosed combustion devices that are used to control process vent emissions from non-dedicated PMPU's at a facility. Centralized combustion control devices may also be used to control emissions from source types including, but not limited to, storage tanks, waste management units, and equipment leaks.

Cleaning operation means routine rinsing, washing, or boil-off of equipment in batch operations between batches.

Closed biological treatment process means a tank or surface impoundment where biological treatment occurs and air emissions from the treatment process are routed to either a control device by means of a closed-vent system or by means of hard-piping. The tank or surface impoundment has a fixed roof, as defined in this section, or a floating flexible membrane cover that meets the requirements specified in § 63.1256(c).

Closed-loop system means an enclosed system that returns process fluid to the process and is not vented to the atmosphere except through a closed-vent system.

Closed-purge system means a system or combination of system and portable containers, to capture purged liquids. Containers must be covered or closed when not being filled or emptied.

Closed-vent system means a system that is not open to the atmosphere and is composed of piping, ductwork, connections, and, if necessary, flow inducing devices that transport gas or vapor from an emission point to a control device.

Combustion device means an individual unit of equipment, such as a flare, incinerator, process heater, or boiler, used for the combustion of HAP vapors.

Combustion device burner means a device designed to mix and ignite fuel and air to provide a flame to heat and oxidize waste organic vapors in a combustion device.

Connector means flanged, screwed, or other joined fittings used to connect two pipe lines or a pipe line and a piece of equipment. A common connector is a flange. Joined fittings welded completely around the circumference of the interface are not considered connectors for the purpose of this regulation. For the purpose of reporting and recordkeeping, connector means joined fittings that are not inaccessible, ceramic, or ceramic-lined as described in § 63.1255(b)(1)(vii) and § 63.1255(f)(3).

Construction means the onsite fabrication, erection, or installation of an affected source or a PMPU. Addition of new equipment to a PMPU subject to existing source standards does not constitute construction, but it may constitute reconstruction of the affected source or PMPU if it satisfies the definition of reconstruction in this section.

Consumption means the quantity of all HAP raw materials entering a process in excess of the theoretical amount used as reactant, assuming 100 percent stoichiometric conversion. The raw materials include reactants, solvents, and any other additives. If a HAP is generated in the process as well as added as a raw material, consumption includes the quantity generated in the process.

Container, as used in the wastewater provisions, means any portable waste management unit that has a capacity greater than or equal to 0.1 m³ in which a material is stored, transported, treated, or otherwise handled. Examples of containers are drums, barrels, tank trucks, barges, dumpsters, tank cars, dump trucks, and ships.

Continuous process means a process where the inputs and outputs flow continuously throughout the duration of the process. Continuous processes are typically steady state.

Continuous recorder means a data recording device that either records an instantaneous data value at least once every 15 minutes or records 15-minute or more frequent block average values.

Continuous seal means a seal that forms a continuous closure that completely covers the space between the wall of the storage tank and the edge of the floating roof. A continuous seal may be a vapor-mounted, liquid-mounted, or metallic shoe seal.

Control device, for purposes of this §63.1255, means any equipment used for recovering or oxidizing organic hazardous air pollutant vapors. Such equipment includes, but is not limited to, absorbers, carbon adsorbers, condensers, flares, boilers, and process heaters.

Controlled HAP emissions means the quantity of HAP discharged to the atmosphere from an air pollution control device.

Cover, as used in the wastewater provisions, means a device or system which is placed on or over a waste management unit containing wastewater or residuals so that the entire surface area is enclosed to minimize air emissions. A cover may have openings necessary for operation, inspection, and maintenance of the waste management unit such as access hatches, sampling ports, and gauge wells provided that each opening is closed when not in use. Examples of covers include a fixed roof installed on a wastewater tank, a lid installed on a container, and an air-supported enclosure installed over a waste management unit.

Dedicated PMPU means a PMPU that is composed of equipment that is used to manufacture the same product for a continuous period of 6 months or greater. The PMPU includes any shared storage tank(s) that are determined to belong to the PMPU according to the procedures in §63.1250(e).

Dense gas system means a conveyance system operated to limit oxygen levels below 12 percent.

Double block and bleed system means two block valves connected in series with a bleed valve or line that can vent the line between the two block valves.

Duct work means a conveyance system such as those commonly used for heating and ventilation systems. It is often made of sheet metal and often has sections connected by screws or crimping. Hard-piping is not ductwork.

Enhanced biological treatment system or enhanced biological treatment process means an aerated, thoroughly mixed treatment unit(s) that contains biomass suspended in water followed by a clarifier that removes biomass from the treated water and recycles recovered biomass to the aeration unit. The mixed liquor volatile suspended solids (biomass) is greater than 1 kilogram per cubic meter throughout each aeration unit. The biomass is suspended and aerated in the water of the aeration unit(s) by either submerged air flow or mechanical agitation. A thoroughly mixed treatment unit is a unit that is designed and operated to approach or achieve uniform biomass distribution and organic compound concentration throughout the aeration unit by quickly dispersing the recycled biomass and the wastewater entering the unit.

Equipment, for purposes of §63.1255, means each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, and instrumentation system in organic hazardous air pollutant service; and any control devices or closed-vent systems required by this subpart.

Excipient means any substance other than the active drug or product which has been appropriately evaluated for safety and is included in a drug delivery system to either aid the processing of the drug delivery system during its manufacture; protect, support, or enhance stability, bioavailability, or patient acceptability; assist in product identification; or enhance any other attribute of the overall safety and effectiveness of the drug delivery system during storage or use.

External floating roof means a pontoon-type or double-deck type cover that rests on the liquid surface in a

storage tank or waste management unit with no fixed roof.

Fill or filling means the introduction of material into a storage tank or the introduction of a wastewater stream or residual into a waste management unit, but not necessarily to complete capacity.

First attempt at repair means to take action for the purpose of stopping or reducing leakage of organic material to the atmosphere.

Fixed roof means a cover that is mounted on a waste management unit or storage tank in a stationary manner and that does not move with fluctuations in liquid level.

Floating roof means a cover consisting of a double deck, pontoon single deck, internal floating cover or covered floating roof, which rests upon and is supported by the liquid being contained, and is equipped with a closure seal or seals to close the space between the roof edge and waste management unit or storage tank wall.

Flow indicator means a device which indicates whether gas flow is, or whether the valve position would allow gas flow to be, present in a line.

Formulation means the process of mixing, blending, or diluting one or more active or inert ingredients with one or more active or inert ingredients, without an intended chemical reaction, to obtain a pharmaceutical dosage form. Formulation operations include mixing, compounding, blending, and tablet coating.

Group of processes means all of the equipment associated with processes in a building, processing area, or facility-wide. For a dedicated process, a group of processes may consist of a single process.

Halogen atoms mean atoms of chlorine or fluorine.

Halogenated compounds means organic HAP compounds that contain halogen atoms.

Halogenated vent stream or Halogenated stream means a process, storage tank, or waste management unit vent determined to have a concentration of halogenated compounds of greater than 20 ppmv, as determined through process knowledge, test results using Method 18 of 40 CFR part 60, appendix A, or test results using any other test meth-

od that has been validated according to the procedures in Method 301 of appendix A of this part.

Hard-piping means piping or tubing that is manufactured and properly installed using good engineering judgment and standards, such as ANSI B31-3.

Hydrogen halides and halogens means hydrogen chloride (HCl), chlorine (Cl²), and hydrogen fluoride (HF).

In gas/vapor service means that a piece of equipment in organic hazardous air pollutant service contains a gas or vapor at operating conditions.

In heavy liquid service means that a piece of equipment in organic hazardous air pollutant service is not in gas/vapor service or in light liquid service.

In light liquid service means that a piece of equipment in organic hazardous air pollutant service contains a liquid that meets the following conditions:

(1) The vapor pressure of one or more of the organic compounds is greater than 0.3 kilopascals at 20 °C;

(2) The total concentration of the pure organic compounds constituents having a vapor pressure greater than 0.3 kilopascals at 20 °C is equal to or greater than 20 percent by weight of the total process stream; and

(3) The fluid is a liquid at operating conditions. (Note: Vapor pressures may be determined by the methods described in 40 CFR 60.485(e)(1).)

In liquid service means that a piece of equipment in organic hazardous air pollutant service is not in gas/vapor service.

In organic hazardous air pollutant or in organic HAP service means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight of total organic HAP's as determined according to the provisions of § 63.180(d). The provisions of § 63.180(d) also specify how to determine that a piece of equipment is not in organic HAP service.

In vacuum service means that equipment is operating at an internal pressure which is at least 5 kilopascals below ambient pressure.

In-situ sampling systems means non-extractive samplers or in-line samplers.

Individual drain system means the stationary system used to convey wastewater streams or residuals to a waste management unit. The term includes hard piping; all process drains and junction boxes; and associated sewer lines, other junction boxes, manholes, sumps, and lift stations conveying wastewater streams or residuals. A segregated stormwater sewer system, which is a drain and collection system designed and operated for the sole purpose of collecting rainfall-runoff at a facility, and which is segregated from all other individual drain systems, is excluded from this definition.

Initial startup means the first time a new or reconstructed source begins production. Initial startup does not include operation solely for testing equipment. Initial startup does not include subsequent start ups (as defined in this section) of processes following malfunctions or process shutdowns.

Internal floating roof means a cover that rests or floats on the liquid surface (but not necessarily in complete contact with it) inside a storage tank or waste management unit that has a permanently affixed roof.

Instrumentation system means a group of equipment components used to condition and convey a sample of the process fluid to analyzers and instruments for the purpose of determining process operating conditions (e.g., composition, pressure, flow, etc.). Valves and connectors are the predominant type of equipment used in instrumentation systems; however, other types of equipment may also be included in these systems. Only valves nominally 0.5 inches and smaller, and connectors nominally 0.75 inches and smaller in diameter are considered instrumentation systems for the purposes of this subpart. Valves greater than nominally 0.5 inches and connectors greater than nominally 0.75 inches associated with instrumentation systems are not considered part of instrumentation systems and must be monitored individually.

Isolated intermediate means a product of a process. An isolated intermediate is usually a product of a chemical synthesis, fermentation, or biological extraction process; several different isolated intermediates may be produced

in the manufacture of a finished dosage form of a drug. Precursors, active ingredients, or finished dosage forms are considered isolated intermediates. An isolated intermediate is stored before subsequent processing. Storage occurs at any time the intermediate is placed in equipment used solely for storage, such as drums, totes, day tanks, and storage tanks. The storage of an isolated intermediate marks the end of a process.

Junction box means a manhole or access point to a wastewater sewer system line or a lift station.

Large control device means a control device that controls total HAP emissions of greater than or equal to 10 tons/yr, before control.

Liquid-mounted seal means a foam- or liquid-filled seal mounted in contact with the liquid between the wall of the storage tank or waste management unit and the floating roof. The seal is mounted continuously around the tank or unit.

Liquids dripping means any visible leakage from the seal including dripping, spraying, misting, clouding, and ice formation. Indications of liquid dripping include puddling or new stains that are indicative of an existing evaporated drip.

Maintenance wastewater means wastewater generated by the draining of process fluid from components in the pharmaceutical manufacturing process unit into an individual drain system in preparation for or during maintenance activities. Maintenance wastewater can be generated during planned and unplanned shutdowns and during periods not associated with a shutdown. Examples of activities that can generate maintenance wastewater include descaling of heat exchanger tubing bundles, cleaning of distillation column traps, draining of pumps into an individual drain system, and draining of portions of the pharmaceutical manufacturing process unit for repair. Wastewater from cleaning operations is not considered maintenance wastewater.

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, emissions monitoring equipment, process equipment, or a process

to operate in a normal or usual manner. Failures that are caused all or in part by poor maintenance or careless operation are not malfunctions.

Maximum true vapor pressure means the equilibrium partial pressure exerted by the total organic HAP in the stored or transferred liquid at the temperature equal to the highest calendar-month average of the liquid storage or transferred temperature for liquids stored or transferred above or below the ambient temperature or at the local maximum monthly average temperature as reported by the National Weather Service for liquids stored or transferred at the ambient temperature, as determined:

(1) In accordance with methods described in Chapter 19.2 of the American Petroleum Institute's Manual of Petroleum Measurement Standards, Evaporative Loss From Floating-Roof Tanks (incorporated by reference as specified in § 63.14); or

(2) As obtained from standard reference texts; or

(3) As determined by the American Society for Testing and Materials Method D2879-97, Test Method for Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope (incorporated by reference as specified in § 63.14); or

(4) Any other method approved by the Administrator.

Metallic shoe seal or mechanical shoe seal means metal sheets that are held vertically against the wall of the storage tank by springs, weighted levers, or other mechanisms and connected to the floating roof by braces or other means. A flexible coated fabric (envelope) spans the annular space between the metal sheet and the floating roof.

Nondedicated formulation operations means equipment used to formulate numerous products.

Nondedicated recovery device(s) means a recovery device that receives material from more than one PMPU.

Nonrepairable means that it is technically infeasible to repair a piece of equipment from which a leak has been detected without a process shutdown.

Open biological treatment process means a biological treatment process

that is not a closed biological treatment process as defined in this section.

Open-ended valve or line means any valve, except pressure relief valves, having one side of the valve seat in contact with process fluid and one side open to atmosphere, either directly or through open piping.

Operating scenario for the purposes of reporting and recordkeeping, means any specific operation of a PMPU and includes for each process:

(1) A description of the process and the type of process equipment used;

(2) An identification of related process vents and their associated emissions episodes and durations, wastewater PODs, and storage tanks;

(3) The applicable control requirements of this subpart, including the level of required control, and for vents, the level of control for each vent;

(4) The control or treatment devices used, as applicable, including a description of operating and/or testing conditions for any associated control device;

(5) The process vents, wastewater PODs, and storage tanks (including those from other processes) that are simultaneously routed to the control or treatment device(s);

(6) The applicable monitoring requirements of this subpart and any parametric level that assures compliance for all emissions routed to the control or treatment device;

(7) Calculations and engineering analyses required to demonstrate compliance; and

(8) For reporting purposes, a change to any of these elements not previously reported, except for paragraph (5) of this definition, shall constitute a new operating scenario.

Partially soluble HAP means a HAP listed in Table 2 of this subpart.

Pharmaceutical manufacturing operations means the facilitywide collection of PMPU and any other equipment such as heat exchanger systems, wastewater and waste management units, or cooling towers that are not associated with an individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical products and are under common control.

Pharmaceutical manufacturing process unit (PMPU) means the process, as defined in this subpart, and any associated storage tanks, equipment identified in § 63.1252(f), and components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.

Pharmaceutical product means any of the following materials, excluding any material that is a nonreactive solvent, excipient, binder, or filler, or any material that is produced in a chemical manufacturing process unit that is subject to the requirements of subparts F and G of this part 63:

(1) Any material described by the standard industrial classification (SIC) code 2833 or 2834; or

(2) Any material whose manufacturing process is described by North American Industrial Classification System (NAICS) code 325411 or 325412; or

(3) A finished dosage form of a drug, for example, a tablet, capsule, solution, etc.; or

(4) Any active ingredient or precursor that is produced at a facility whose primary manufacturing operations are described by SIC code 2833 or 2834; or

(5) At a facility whose primary operations are not described by SIC code 2833 or 2834, any material whose primary use is as an active ingredient or precursor.

Plant site means all contiguous or adjoining property that is under common control, including properties that are separated only by a road or other public right-of-way. Common control includes properties that are owned, leased, or operated by the same entity, parent entity, subsidiary, or any combination thereof.

Point of determination (POD) means the point where a wastewater stream exits the process, storage tank, or last recovery device. If soluble and/or partially soluble HAP compounds are not recovered from water before discharge, the discharge point from the process equipment or storage tank is a POD. If water streams are routed to a recovery device, the discharge from the recovery

device is a POD. There can be more than 1 POD per process or PMPU.

Precursor means a material that is manufactured to undergo further chemical change or processing to ultimately manufacture an active ingredient or finished dosage form of a drug. This term does not include commodity chemicals produced by the synthetic organic chemical manufacturing industry.

Pressure release means the emission of materials resulting from the system pressure being greater than the set pressure of the pressure relief device. This release can be one release or a series of releases over a short time period due to a malfunction in the process.

Pressure relief device or valve means a safety device used to prevent operating pressures from exceeding the maximum allowable working pressure of the process equipment. A common pressure relief device is a spring-loaded pressure relief valve. Devices that are actuated either by a pressure of less than or equal to 2.5 psig or by a vacuum are not pressure relief devices.

Primary use means 50 percent or more of a material is used for a particular purpose.

Process means all equipment which collectively function to produce a pharmaceutical product or isolated intermediate (which is also a pharmaceutical product). A process may consist of one or more unit operations. For the purposes of this subpart, process includes any, all, or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a pharmaceutical product or isolated intermediate. Cleaning operations conducted are considered part of the process. Nondedicated solvent recovery operations located within a contiguous area within the affected source are considered single processes. A storage tank that is used to accumulate used solvent from multiple batches of a single process for purposes of solvent recovery does not represent the end of the process. Nondedicated formulation operations occurring within a contiguous area are considered a single process that is used to formulate numerous materials and/or products. Quality assurance and

quality control laboratories are not considered part of any process. Ancillary activities are not considered a process or part of any process. Ancillary activities include boilers and incinerators (not used to comply with the provisions of § 63.1253, § 63.1254, or § 63.1256(h)), chillers and refrigeration systems, and other equipment and activities that are not directly involved (*i.e.*, they operate within a closed system and materials are not combined with process fluids) in the processing of raw materials or the manufacturing of a pharmaceutical product.

Process condenser means a condenser whose primary purpose is to recover material as an integral part of a process. The condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are at or above the boiling or bubble point of substance(s) at the liquid surface. Examples of process condensers include distillation condensers, reflux condensers, and condensers used in stripping or flashing operations. In a series of condensers, all condensers up to and including the first condenser with an exit gas temperature below the boiling or bubble point of the substance(s) at the liquid surface are considered to be process condensers. All condensers in line prior to a vacuum source are included in this definition.

Process shutdown means a work practice or operational procedure that stops production from a process or part of a process during which it is technically feasible to clear process material from a process or part of a process consistent with safety constraints and during which repairs can be effected. An unscheduled work practice or operational procedure that stops production from a process or part of a process for less than 24 hours is not a process shutdown. An unscheduled work practice or operational procedure that would stop production from a process or part of a process for a shorter period of time than would be required to clear the process or part of the process of materials and start up the process, and would result in greater emissions than delay of repair of leaking components until the next scheduled process shutdown, is not a process shutdown. The use of spare equipment and technically

feasible bypassing of equipment without stopping production are not process shutdowns.

Process tank means a tank that is used to collect material discharged from a feedstock storage tank or unit operation and to transfer this material to another unit operation within the process or to a product storage tank. Surge control vessels and bottoms receivers that fit these conditions are considered process tanks. Product storage tanks are considered process tanks and are part of the PMPU that produce the stored material. For the purposes of this subpart, vents from process tanks are considered process vents.

Process vent means a vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Emission streams that are undiluted and uncontrolled containing less than 50 ppmv HAP, as determined through process knowledge that no HAP are present in the emission stream or using an engineering assessment as discussed in § 63.1257(d)(2)(ii), test data using Methods 18 of 40 CFR part 60, appendix A, or any other test method that has been validated according to the procedures in Method 301 of appendix A of this part, are not considered process vents. Process vents do not include vents on storage tanks regulated under § 63.1253, vents on wastewater emission sources regulated under § 63.1256, or pieces of equipment regulated under § 63.1255.

Production-indexed HAP consumption factor is the result of dividing the annual consumption of total HAP by the annual production rate, per process.

Production-indexed volatile organic compound (VOC) consumption factor is the result of dividing the annual consumption of total VOC by the annual production rate, per process.

Publicly owned treatment works (POTW) means any devices and systems

used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature as defined in section 212(2)(A) of the Clean Water Act, as amended [33 U.S.C. § 1292(2)(A)]. A POTW includes the treatment works, intercepting sewers, outfall sewers, sewage collection systems, pumping, power, and other equipment. The POTW is defined at 40 CFR 403.3(o).

Reactor means a device or vessel in which one or more chemicals or reactants, other than air, are combined or decomposed in such a way that their molecular structures are altered and one or more new organic compounds are formed.

Reconstruction, as used in § 63.1250(b), shall have the meaning given in § 63.2, except that “affected or previously unaffected stationary source” shall mean either “affected facility” or “PMPU.” As used in § 63.1254(a)(3)(ii)(A)(3), reconstruction shall have the meaning given in § 63.2, except that “source” shall mean “control device.”

Recovery device, as used in the wastewater provisions, means an individual unit of equipment used for the purpose of recovering chemicals for fuel value (i.e., net positive heating value), use, reuse, or for sale for fuel value, use or reuse. Examples of equipment that may be recovery devices include organic removal devices such as decanters, strippers, or thin-film evaporation units. To be a recovery device, a decanter and any other equipment based on the operating principle of gravity separation must receive only two-phase liquid streams.

Repaired means that equipment:

- (1) Is adjusted, or otherwise altered, to eliminate a leak as defined in the applicable paragraphs of § 63.1255, and;
- (2) Is, unless otherwise specified in applicable provisions of § 63.1255, monitored as specified in § 63.180(b) and (c) as appropriate, to verify that emissions from the equipment are below the applicable leak definition.

Research and development facility means any stationary source whose primary purpose is to conduct research and development into new processes and products, where such source is operated under the close supervision of technically trained personnel, and is

not engaged in the manufacture of products for commercial sale in commerce, except in a de minimis manner.

Residual means any HAP-containing liquid or solid material that is removed from a wastewater stream by a waste management unit or treatment process that does not destroy organics (non-destructive unit). Examples of residuals from nondestructive waste management units are: the organic layer and bottom residue removed by a decanter or organic-water separator and the overheads from a steam stripper or air stripper. Examples of materials which are not residuals are: silt; mud; leaves; bottoms from a steam stripper or air stripper; and sludges, ash, or other materials removed from wastewater being treated by destructive devices such as biological treatment units and incinerators.

Safety device means a closure device such as a pressure relief valve, frangible disc, fusible plug, or any other type of device which functions exclusively to prevent physical damage or permanent deformation to a unit or its air emission control equipment by venting gases or vapors directly to the atmosphere during unsafe conditions resulting from an unplanned, accidental, or emergency event. For the purposes of this subpart, a safety device is not used for routine venting of gases or vapors from the vapor headspace underneath a cover such as during filling of the unit or to adjust the pressure in this vapor headspace in response to normal daily diurnal ambient temperature fluctuations. A safety device is designed to remain in a closed position during normal operations and open only when the internal pressure, or another relevant parameter, exceeds the device threshold setting applicable to the air emission control equipment as determined by the owner or operator based on manufacturer recommendations, applicable regulations, fire protection and prevention codes, standard engineering codes and practices, or other requirements for the safe handling of flammable, combustible, explosive, reactive, or hazardous materials.

Sampling connection system means an assembly of equipment within a process unit used during periods of representative operation to take samples

of the process fluid. Equipment used to take nonroutine grab samples is not considered a sampling connection system.

Sensor means a device that measures a physical quantity or the change in a physical quantity, such as temperature, pressure, flow rate, pH, or liquid level.

Set pressure means the pressure at which a properly operating pressure relief device begins to open to relieve atypical process system operating pressure.

Sewer line means a lateral, trunk line, branch line, or other conduit including, but not limited to, grates, trenches, etc., used to convey wastewater streams or residuals to a downstream waste management unit.

Shutdown means the cessation of operation of a continuous process for any purpose. Shutdown also means the cessation of a batch process or any related individual piece of equipment required or used to comply with this subpart as a result of a malfunction or for replacement of equipment, repair, or any other purpose not excluded from this definition. Shutdown also applies to emptying and degassing storage vessels. Shutdown does not apply to cessation of a batch process at the end of a campaign, for routine maintenance, for rinsing or washing of equipment between batches, or other routine operations.

Single-seal system means a floating roof having one continuous seal that completely covers the space between the wall of the storage tank and the edge of the floating roof. This seal may be a vapor-mounted, liquid-mounted, or metallic shoe seal.

Small control device means a control device that controls total HAP emissions of less than 10 tons/yr, before control.

Soluble HAP means a HAP listed in Table 3 of this subpart.

Standard batch means a batch process operated within a range of operating conditions that are documented in an operating scenario. Emissions from a standard batch are based on the operating conditions that result in highest emissions. The standard batch defines the uncontrolled and controlled emis-

sions for each emission episode defined under the operating scenario.

Startup means the setting in operation of a continuous process unit for any purpose; the first time a new or reconstructed batch process unit begins production; for new equipment added, including equipment used to comply with this subpart, the first time the equipment is put into operation; or, for the introduction of a new product/process, the first time the product or process is run in equipment. For batch process units, startup does not apply to the first time the equipment is put into operation at the start of a campaign to produce a product that has been produced in the past, after a shutdown for maintenance, or when the equipment is put into operation as part of a batch within a campaign. As used in § 63.1255, startup means the setting in operation of a piece of equipment or a control device that is subject to this subpart.

Storage tank means a tank or other vessel that is used to store organic liquids that contain one or more HAP as raw material feedstocks. Storage tank also means a tank or other vessel in a tank farm that receives and accumulates used solvent from multiple batches of a process or processes for purposes of solvent recovery. The following are not considered storage tanks for the purposes of this subpart:

- (1) Vessels permanently attached to motor vehicles such as trucks, railcars, barges, or ships;
- (2) Pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere;
- (3) Vessels storing organic liquids that contain HAP only as impurities;
- (4) Wastewater storage tanks; and
- (5) Process tanks (including product tanks and isolated intermediate tanks).

Supplemental gases are any gaseous streams that are not defined as process vents, or closed-vent systems from wastewater management and treatment units, storage tanks, or equipment components and that contain less than 50 ppmv TOC, as determined through process knowledge, that are introduced into vent streams or manifolds. Air required to operate combustion device burner(s) is not considered supplemental gas.

Surface impoundment means a waste management unit which is a natural topographic depression, manmade excavation, or diked area formed primarily of earthen materials (although it may be lined with manmade materials), which is designed to hold an accumulation of liquid wastes or waste containing free liquids. A surface impoundment is used for the purpose of treating, storing, or disposing of wastewater or residuals, and is not an injection well. Examples of surface impoundments are equalization, settling, and aeration pits, ponds, and lagoons.

System flowrate means the flowrate of gas entering the control device.

Total organic compounds (TOC) means those compounds measured according to the procedures of Method 18 or Method 25A, 40 CFR part 60, appendix A.

Treatment process means a specific technique that removes or destroys the organics in a wastewater or residual stream such as a steam stripping unit, thin-film evaporation unit, waste incinerator, biological treatment unit, or any other process applied to wastewater streams or residuals to comply with § 63.1256. Most treatment processes are conducted in tanks. Treatment processes are a subset of waste management units.

Uncontrolled HAP emissions means a gas stream containing HAP which has exited the process (or process condenser, if any), but which has not yet 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

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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.

[63 FR 50326, Sept. 21, 1998, as amended at 65 FR 52598, Aug. 29, 2000]

§ 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 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.