

- i. Each dual mechanical seal system is:
  - a) Operated with the barrier fluid at a pressure that is at all times greater than the pump/agitator stuffing box pressure; or
  - b) Equipped with a barrier fluid degassing reservoir that is connected by a closed-vent system to a control equipment that complies with the requirements of paragraph (b)(4)(ii) of §63.1255; or
  - c) Equipped with a closed-loop system that purges the barrier fluid into a process stream.
- ii. The barrier fluid is not in light liquid service.
- iii. Each barrier fluid system is equipped with a sensor that will detect failure of the seal system, the barrier fluid system, or both.
- iv. Each pump/agitator is checked by visual inspection each calendar week for indications of liquids dripping from the pump/agitator seal. If there are indications of liquids dripping from the pump or agitator seal at the time of the weekly inspection, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall follow the procedures specified in either paragraph I(5)(iv)(A) or (B) of §63.1255 prior to the next required inspection. [40 CFR §63.1255(c)(5)(iv)]
  - a) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor the pump or agitator using the method specified in §63.180(b) to determine if there is a leak of organic HAP in the barrier fluid. If the instrument reading indicates a leak, as specified in paragraph (c)(2)(ii) of §63.1255, a leak is detected. [40 CFR §63.1255(c)(5)(iv)(A)]
  - b) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall eliminate the visual indications of liquids dripping. [40 CFR §63.1255I(5)(iv)(B)]
- v. Each sensor as described in paragraph I(5)(iii) of §63.1255 is observed daily or is equipped with an alarm unless the pump is located within the boundary of an unmanned plant site. [40 CFR §63.1255I(5)(v)]
- vi. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) determines based on design considerations and operating experience, the criterium applicable to the presence and frequency of drips and to the sensor that indicates failure of the seal system, the barrier fluid system, or both. [40 CFR §63.1255I(5)(vi)(A)]

- vii. If indications of liquids dripping from the pump/agitator seal exceed the criterium established in paragraph I(5)(vi)(A) of §63.1255, or if, based on the criterium established in paragraph (c)(5)(vi)(A) of §63.1255, the sensor indicates failure of the seal system, the barrier fluid system, or both, a leak is detected. [40 CFR §63.1255(c)(5)(vi)(B)]
- viii. When a leak is detected pursuant to paragraph I(5)(iv)(A) or (B) of §63.1255, the leak must be repaired as specified in paragraph (c)(3) of §63.1255. [40 CFR §63.1255(c)(5)(vii)]
- h. Any pump/agitator that is designed with no externally actuated shaft penetrating the pump/agitator housing is exempt from the requirements of paragraphs I(1) through (3) of §63.1255. [40 CFR §63.1255I(6)]
- i. Any pump/agitator equipped with a closed-vent system capable of capturing and transporting any leakage from the seal or seals back to the process or to a control equipment that complies with the requirements of paragraph (b)(4)(ii) of §63.1255 is exempt from the requirements of paragraphs (c)(2) through (5) of §63.1255. [40 CFR §63.1255(c)(7)]
- j. Any pump/agitator that is located within the boundary of an unmanned plant site is exempt from the weekly visual inspection requirement of paragraphs I(2)(iii) and I(5)(iv) of §63.1255 and the daily requirements of paragraph I(5)(v) of §63.1255, provided that each pump/agitator is visually inspected as often as practicable and at least monthly. [40 CFR §63.1255I(8)]
- k. more than 90 percent of the pumps in a group of processes meet the criteria in either paragraph I(5) or (6) of §63.1255, the group of processes is exempt from the requirements of paragraph I(4) of §63.1255. [40 CFR §63.1255I(9)]
- 4. *Standards: Open-Ended Valves or Lines.*
  - a. Each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in §63.177 and paragraphs (d)(4) through (6) of §63.1255. [40 CFR §63.1255(d)(1)(i)]
  - b. The cap, blind flange, plug, or second valve shall seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair. The cap, blind flange, plug, or second valve shall be in place within 1 hour of cessation of operations requiring process fluid flow through the open-ended valve or line, or within 1 hour of cessation of maintenance or repair. The owner or operator is not required to keep a record documenting compliance with the 1-hour requirement. [40 CFR §63.1255(d)(1)(ii)]

- c. Each open-ended valve or line equipped with a second valve shall be operated in a manner such that the valve on the process fluid end is closed before the second valve is closed. [40 CFR §63.1255(d)(2)]
  - d. When a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with paragraph (d)(1) of §63.1255 at all other times. [40 CFR §63.1255(d)(3)]
  - e. Open-ended valves or lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are exempt from the requirements of paragraphs (d)(1) through (d)(3) of §63.1255. [40 CFR §63.1255(d)(4)]
  - f. Open-ended valves or lines containing materials which would auto catalytically polymerize are exempt from the requirements of paragraphs (d)(1) through (d)(3) of §63.1255. [40 CFR §63.1255(d)(5)]
  - g. Open-ended valves or lines containing materials which could cause an explosion, serious overpressure, or other safety hazard if capped or equipped with a double block and bleed system as specified in paragraphs (d)(1) through (d)(3) of §63.1255 are exempt from the requirements of paragraphs (d)(1) through (d)(3) of §63.1255. [40 CFR §63.1255(d)(6)]
5. *Standards - Valves in Gas/Vapor Service and in Light Liquid Service.*
- a. The provisions of §63.1255 apply to valves that are either in gas organic HAP service or in light liquid organic HAP service. [40 CFR §63.1255(e)(1)]
  - b. For existing and new affected sources, all valves subject to §63.1255 shall be monitored, except as provided in paragraph (f) of §63.1255 and in §63.177, by no later than 1 year after the compliance date. [40 CFR §63.1255(e)(2)]
  - c. *Monitoring.* According to 40 CFR §63.1255(e)(3), the owner or operator of a source subject to §63.1255 shall monitor all valves, except as provided in paragraph (f) of §63.1255 and in §63.177, at the intervals specified in paragraph (e)(4) of §63.1255 and shall comply with all other provisions of §63.1255, except as provided in paragraph (b)(4)(ii) of §63.1255 §§63.178 and 63.179.
    - i) The valves shall be monitored to detect leaks by the method specified in §63.180(b).
    - ii) An instrument reading of 500 parts per million or greater defines a leak.
  - d. *Subsequent monitoring frequencies.* According to 40 CFR §63.1255(e)(4), after conducting the initial survey required in paragraph (e)(2) of §63.1255, Pfizer

Pharmaceuticals LLC (CRUCE DAVILA) shall monitor valves for leaks at the intervals specified below:

- i. For a group of processes with 2 percent or greater leaking valves, calculated according to paragraph (e)(6) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor each valve once per month, except as specified in paragraph (e)(9) of §63.1255.
  - ii. For a group of processes with less than 2 percent leaking valves, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor each valve once each quarter, except as provided in paragraphs (e)(4)(iii) through (e)(4)(v) of §63.1255.
  - iii. For a group of processes with less than 1 percent leaking valves, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to monitor each valve once every 2 quarters (every six months).
  - iv. For a group of processes with less than 0.5 percent leaking valves, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to monitor each valve once every 4 quarters (every 12 months).
  - v. For a group of processes with less than 0.25 percent leaking valves, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to monitor each valve once every 2 years.
- e. *Calculation of percent leakers.* According to 40 CFR §63.1255(e)(5), For a group of processes to which subpart GGG applies, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may choose to subdivide the valves in the applicable group of processes and apply the provisions of paragraph (e)(4) of §63.1255 to each subgroup. If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to subdivide the valves in the applicable group of processes, then the provisions of paragraphs (e)(5)(i) through (e)(5)(viii) of §63.1255 apply.
- i. The overall performance of total valves in the applicable group of processes must be less than 2 percent leaking valves, as detected according to paragraphs (e)(3) (i) and (ii) of §63.1255 and as calculated according to paragraphs (e)(6) (ii) and (iii) of §63.1255.
  - ii. The initial assignment or subsequent reassignment of valves to subgroups shall be governed by the provisions of paragraphs (e)(5)(ii) (A) through (C) of §63.1255.
    - a) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall determine which valves are assigned to each subgroup. Valves with less than 1 year of monitoring data or valves not monitored within the last 12

months must be placed initially into the most frequently monitored subgroup until at least 1 year of monitoring data has been obtained.

- b) Any valve or subgroup of valves can be reassigned from a less frequently monitored subgroup to a more frequently monitored subgroup provided that the valves to be reassigned were monitored during the most recent monitoring period for the less frequently monitored subgroup. The monitoring results must be included with the less frequently monitored subgroup's monitoring events and associated next percent leaking valves calculation for that group.
  - c) Any valve or group of valves can be reassigned from a more frequently monitored subgroup to a less frequently monitored subgroup provided that the valves to be reassigned have not leaked for the period of the less frequently monitored subgroup (e.g., for the last 12 months, if the valve or group of valves is to be reassigned to a subgroup being monitored annually). Non-repairable valves may not be reassigned to a less frequently monitored subgroup.
- iii. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall determine every 6 months if the overall performance of total valves in the applicable group of processes is less than 2 percent leaking valves and so indicate the performance in the next periodic report. If the overall performance of total valves in the applicable group of processes is 2 percent leaking valves or greater, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall revert to the program required in paragraphs (e)(2) through (e)(4) of §63.1255. The overall performance of total valves in the applicable group of processes shall be calculated as a weighted average of the percent leaking valves of each subgroup according to the following Equation:

$$\%V_{LO} = \frac{\sum_{i=1}^n (\%V_{Li} \times V_i)}{\sum_{i=1}^n V_i}$$

Where:

$\%V_{LO}$  = overall performance of total valves in the applicable group of processes

$\%V_{Li}$  = percent leaking valves in subgroup i, most recent value calculated according to the procedures in paragraphs (e)(6)(ii) and (iii) of §63.1255

$V_i$  = number of valves in subgroup I

n = number of subgroups

- iv. *Records.* In addition to records required by paragraph (g) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall maintain records specified in paragraphs (e)(5)(iv)(A) through (D) of §63.1255.
    - a) Which valves are assigned to each subgroup,
    - b) Monitoring results and calculations made for each subgroup for each monitoring period,
    - c) Which valves are reassigned and when they were reassigned, and
    - d) The results of the semiannual overall performance calculation required in paragraph (e)(5)(iii) of §63.1255.
  - v. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall notify the Board and the EPA no later than 30 days prior to the beginning of the next monitoring period of the decision to subgroup valves. The notification shall identify the participating processes and the valves assigned to each subgroup.
  - vi. *Semiannual reports.* In addition to the information required by paragraph (h)(3) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall submit in the periodic reports the information specified in paragraphs (e)(5)(vi)(A) and (B) of §63.1255.
    - a) Valve reassignments occurring during the reporting period, and
    - b) Results of the semiannual overall performance calculation required by paragraph (e)(5)(iii) of §63.1255.
  - vii. To determine the monitoring frequency for each subgroup, the calculation procedures of paragraph (e)(6)(iii) of §63.1255 shall be used.
  - viii. Except for the overall performance calculations required by paragraphs (e)(5)(i) and (e)(5)(iii) of §63.1255, each subgroup shall be treated as if it were a process for the purposes of applying the provisions of §63.1255.
- f. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall decide no later than the implementation date of subpart GGG or upon revision of an operating permit how to group the processes. Once Pfizer Pharmaceuticals LLC (CRUCE DAVILA) has decided, all subsequent percentage calculations shall be made on the same basis. [40 CFR §63.1255(e)(6)(i)]

- g. According to 40 CFR §63.1255(e)(6)(ii), the percent leaking valves for each group of processes or subgroup shall be determined by the following Equation:

$$\%V_L = [V_L/V_I] \times 100$$

Where:

$\%V_L$  = percent leaking valves as determined through periodic monitoring required in paragraphs (e)(2) through (4) of §63.1255.

$V_L$  = number of leaking valves found excluding those that cannot be repaired as provided in paragraph (e)(6)(iv)(A) of §63.1255.

$V_I$  = total valves monitored, in a monitoring period excluding valves monitored as required by (e)(7)(iii) of §63.1255.

- h. When determining monitoring frequency for each group of processes or subgroup subject to monthly, quarterly, or semiannual monitoring frequencies, the percent leaking valves shall be the arithmetic average of the percent leaking valves from the last two monitoring periods. When determining monitoring frequency for each group of processes or subgroup subject to annual or biennial (once every 2 years) monitoring frequencies, the percent leaking valves shall be the arithmetic average of the percent leaking valves from the last three monitoring periods. [40 CFR §63.1255(e)(6)(iii)]
- i. Non-repairable valves shall be included in the calculation of percent leaking valves the first time the valve is identified as leaking and non-repairable and as required to comply with paragraph (e)(6)(iv)(B) of §63.1255. Otherwise, a number of non-repairable valves (identified and included in the percent leaking calculation in a previous period) up to a maximum of 1 percent of the total number of valves in organic HAP service at a process may be excluded from calculation of percent leaking valves for subsequent monitoring periods. [40 CFR §63.1255(e)(6)(iv)(A)]
- j. If the number of non-repairable valves exceeds 1 percent of the total number of valves in organic HAP service at a process, the number of non-repairable valves exceeding 1 percent of the total number of valves in organic HAP service shall be included in the calculation of percent leaking valves. [40 CFR §63.1255(e)(6)(iv)(B)]
- k. *Repair provisions.*
- i. When a leak is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in paragraph (b)(4)(i) of §63.1255. [40 CFR §63.1255(e)(7)(i)]

- ii. A first attempt at repair shall be made no later than 5 calendar days after each leak is detected. [40 CFR §63.1255(e)(7)(ii)]
- iii. When a leak is repaired, the valve shall be monitored at least once within the first 3 months after its repair. Days that the valve is not in organic HAP service shall not be considered part of this 3-month period. The monitoring required by this paragraph is in addition to the monitoring required to satisfy the definitions of “repaired<sup>5</sup>” and “first attempt at repair<sup>6</sup>”. [40 CFR §63.1255(e)(7)(iii)]
  - a) The monitoring shall be conducted as specified in §63.180(b) and (c) as appropriate to determine whether the valve has resumed leaking.
  - b) The monitoring required by paragraphs (e)(2) through (4) of §63.1255 may be used to satisfy the requirements of paragraph (e)(7)(iii) of §63.1255, if the timing of the monitoring period coincides with the time specified in paragraph (e)(7)(iii) of §63.1255. Alternatively, other monitoring may be performed to satisfy the requirements of paragraph (e)(7)(iii) of §63.1255, regardless of whether the timing of the monitoring period for periodic monitoring coincides with the time specified in paragraph (e)(7)(iii) of §63.1255.
  - c) If a leak is detected by monitoring that is conducted pursuant to paragraph (e)(7)(iii) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall follow the provisions of paragraphs (e)(7)(iii)(1) and (2) of §63.1255 to determine whether that valve must be counted as a leaking valve for purposes of paragraph (e)(6) of §63.1255.
    - 1) If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to use periodic monitoring required by paragraphs (e)(2) through (4) of §63.1255 to satisfy the requirements of paragraph (e)(7)(iii) of §63.1255, then the valve shall be counted as a leaking valve.
    - 2) If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to use other monitoring prior to the periodic monitoring required by paragraphs (e)(2) through (4) of §63.1255 to satisfy the

<sup>5</sup> Repaired means that the equipment has been adjusted or otherwise altered to eliminate the leak as defined in the applicable paragraphs of §63.1255 and is, unless otherwise specified in applicable provisions of §63.1255, monitored as specified in §63.180(b) and (c) as appropriate, to verify that equipment emissions are below the applicable definition for leak. [40 CFR §63.1251]

<sup>6</sup> First attempt at repair means to take action for the purpose of stopping or reducing leakage of organic material to the atmosphere. [40 CFR §63.1251]

requirements of paragraph (e)(7)(iii) of §63.1255, then the valve shall be counted as a leaking valve unless it is repaired and shown by periodic monitoring not to be leaking.

- l. According to 40 CFR §63.1255(e)(8), first attempts at repair include, but are not limited to, the following practices where practicable:
    - a) Tightening of bonnet bolts,
    - b) Replacement of bonnet bolts,
    - c) Tightening of packing gland nuts, and
    - d) Injection of lubricant into lubricated packing.
  - m. Any equipment located at a plant site with fewer than 250 valves in organic HAP service in the affected source is exempt from the requirements for monthly monitoring specified in paragraph (e)(4)(i) of §63.1255. Instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor each valve in organic HAP service for leaks once each quarter, or comply with paragraph (e)(4)(iii), (iv), or (v) of §63.1255, except as provided in paragraph (f) of §63.1255. [40 CFR §63.1255(e)(9)]
6. *Unsafe to monitor, difficult to monitor, and inaccessible equipment.*
- a. According to 40 CFR §63.1255(f)(1), equipment that is designated as unsafe to monitor, difficult to monitor, or inaccessible is exempt from the monitoring requirements as specified in paragraphs (f)(1)(i) through (iv) of §63.1255 provided Pfizer Pharmaceuticals LLC (CRUCE DAVILA) meets the requirements specified in paragraph (f)(2), (3), or (4) of §63.1255, as applicable. All equipment must be assigned to a group of processes. Ceramic or ceramic-lined connectors are subject to the same requirements as inaccessible connectors.
    - i. For pumps and agitators, paragraphs (c)(2), (3), and (4) of §63.1255 do not apply.
    - ii. For valves, paragraphs (e)(2) through (7) of §63.1255 do not apply.
    - iii. For connectors, §63.174(b) through (e) and paragraphs (b)(4)(iii)(B) through (F) of §63.1255 do not apply.
    - iv. For closed-vent systems, §63.172(f)(1) and (2) and §63.172(g) do not apply.
  - b. *Equipment that is unsafe to monitor or unsafe to inspect.*

- i. Valves, connectors, agitators, and pumps may be designated as unsafe to monitor if Pfizer Pharmaceuticals LLC (CRUCE DAVILA) determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements referred to in paragraphs (f)(1)(i) through (iii) of §63.1255. [40 CFR §63.1255(f)(2)(i)]
  - ii. Any part of a closed-vent system may be designated as unsafe to inspect if the owner or operator determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements referred to in paragraph (f)(1)(iv) of §63.1255. [40 CFR §63.1255(f)(2)(ii)]
  - iii. The owner or operator of equipment that is designated as unsafe to monitor must have a written plan that requires monitoring of the equipment as frequently as practicable during safe to monitor times, but not more frequently than the periodic monitoring schedule otherwise applicable to the group of processes in which the equipment is located. [40 CFR §63.1255(f)(2)(iii)]
  - iv. For any parts of a closed-vent system designated as unsafe to inspect, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must have a written plan that requires inspection of the closed-vent systems as frequently as practicable during safe to inspect times, but not more frequently than annually. [40 CFR §63.1255(f)(2)(iv)]
- c. *Equipment that is difficult to monitor.*
- i. A valve, agitator, or pump may be designated as difficult to monitor if Pfizer Pharmaceuticals LLC (CRUCE DAVILA) determines that the valve, agitator, or pump cannot be monitored without elevating the monitoring personnel more than 2 meters above a support surface, or it is not accessible in a safe manner when it is in organic HAP service. [40 CFR §63.1255(f)(3)(i)]
  - ii. Any part of a closed-vent system may be designated as difficult to inspect if Pfizer Pharmaceuticals LLC (CRUCE DAVILA) determines that the equipment cannot be inspected without elevating the monitoring personnel more than 2 meters above a support surface, or it is not accessible in a safe manner when it is in organic HAP service. [40 CFR §63.1255(f)(3)(ii)]
  - iii. At an existing source, any valve, agitator or pump within a group of processes that meets the criteria of paragraph (f)(3)(i) of §63.1255 may be designated as difficult to monitor, and any parts of a closed-vent system that meet the requirements of paragraph (f)(3)(ii) of §63.1255 may be designated as difficult to inspect. At a new affected source, Pfizer Pharmaceuticals LLC (CRUCE

DAVILA) may designate no more than 3 percent of valves as difficult to monitor. [40 CFR §63.1255(f)(3)(iii)]

- iv. The owner or operator of valves, agitators, or pumps designated as difficult to monitor must have a written plan that requires monitoring of the equipment at least once per calendar year or on the periodic monitoring schedule otherwise applicable to the group of processes in which the equipment is located, whichever is less frequent. For any part of a closed-vent system designated as difficult to inspect, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must have a written plan that requires inspection of the closed-vent system at least once every 5 years. [40 CFR §63.1255(f)(3)(iv)]

d. *Inaccessible equipment and ceramic or ceramic-lined connectors.*

- i. According to 40 CFR §63.1255(f)(4)(i), a connector may be designated as inaccessible if it is:

- a) Buried;
- b) Insulated in a manner that prevents access to the connector by a monitor probe;
- c) Obstructed by equipment or piping that prevents access to the connector by a monitor probe;
- d) Unable to be reached from a wheeled scissor-lift or hydraulic-type staircase which would allow access to equipment up to 7.6 meters (25 feet) above the ground; or
- e) Not able to be accessed at any time in a safe manner to perform monitoring. Unsafe access includes, but is not limited to, the use of a wheeled scissor-lift on unstable or uneven terrain, the use of a motorized man-lift basket in areas where an ignition potential exists, or access would require near proximity to hazards such as electrical lines, or would risk damage to equipment.

- ii. A connector may be designated as inaccessible if it would require elevating the monitoring personnel more than 2 meters above a permanent support surface or would require the erection of a staircase. [40 CFR §63.1255(f)(4)(ii)]

- iii. At an existing source, any connector that meets the criteria of paragraph (f)(4)(i) or (ii) of §63.1255 may be designated as inaccessible. At a new affected source, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may

designate no more than 3 percent of connectors as inaccessible. [40 CFR §63.1255(f)(4)(iii)]

- iv. If any ceramic, or ceramic-lined connector is observed by visual, audible, olfactory, or other means to be leaking, the leak shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in paragraph (b)(4)(i) of §63.1255. [40 CFR §63.1255(f)(4)(iv)]
- v. Any connector that is inaccessible or that is ceramic or ceramic-lined is exempt from the recordkeeping and reporting requirements of paragraphs (g) and (h) of §63.1255. [40 CFR §63.1255(f)(4)(v)]

**7. Recordkeeping Requirements. (E)(7)**

- a. An owner or operator of more than one group of processes subject to the provisions of §63.1255 may comply with the recordkeeping requirements for the groups of processes in one recordkeeping system if the system identifies with each record the program being implemented (e.g., quarterly monitoring) for each type of equipment. All records and information required by §63.1255 shall be maintained in a manner that can be readily accessed at the plant site. This could include physically locating the records at the plant site or accessing the records from a central location by computer at the plant site. [40 CFR §63.1255(g)(1)]
- b. *General recordkeeping.* According to 40 CFR §63.1255(g)(2), except as provided in paragraph (g)(5)(i) of §63.1255 and in paragraph (a)(9) of §63.1255, the following information pertaining to all equipment subject to the requirements in §63.1255 shall be recorded:
  - i. A list of identification numbers for equipment (except connectors that are subject to paragraph (f)(4) of §63.1255) subject to the requirements of §63.1255. Except for equipment subject to the recordkeeping requirements in paragraphs (g)(2)(ii) through (viii) of §63.1255, equipment need not be physically identified if, for a particular type of equipment, all items of that equipment in a designated area or length of pipe subject to the provisions of §63.1255 are identified as a group, and the number of subject items of equipment is indicated. The list for each type of equipment shall be completed no later than the completion of the initial survey required for that component. The list of identification numbers shall be updated, if needed, to incorporate equipment changes identified during the course of each monitoring period within 90 calendar days, or by the next Periodic Report, following the end of the monitoring period for the type of equipment component monitored, whichever is later. [40 CFR §63.1255(g)(2)(i)(A)]

- ii. A schedule for monitoring connectors subject to the provisions of §63.174(a) and valves subject to the provisions of paragraph (e)(4) of §63.1255. [40 CFR §63.1255(g)(2)(i)(B)]
- iii. Physical tagging of the equipment to indicate that it is in organic HAP service is not required. Equipment subject to the provisions of §63.1255 may be identified on a plant site plan, in log entries, or by other appropriate methods. [40 CFR §63.1255(g)(2)(i)I]
- iv. A list of identification numbers for equipment that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to equip with a closed-vent system and control equipment, under the provisions of paragraph I(7) of §63.1255, §63.164(h), or §63.165I. [40 CFR §63.1255(g)(2)(ii)(A)]
- v. A list of identification numbers for pressure relief equipment subject to the provisions in §63.165(a). [40 CFR §63.1255(g)(2)(iii)(A)]
- vi. A list of identification numbers for pressure relief equipment equipped with rupture disks, under the provisions of §63.165(d). [40 CFR §63.1255(g)(2)(iii)(B)]
- vii. Identification of instrumentation systems subject to the provisions of §63.1255. Individual components in an instrumentation system need not be identified. [40 CFR §63.1255(g)(2)(iv)]
- viii. According to 40 CFR §63.1255(g)(2)(v), the following information shall be recorded for each dual mechanical seal system:
  - a) Design criteria required by paragraph I(5)(vi)(A) of section §63.1255 and §63.164(e)(2), and an explanation of the design criteria; and
  - b) Any changes to these criteria and the reasons for the changes.
- ix. A list of equipment designated as unsafe to monitor/inspect or difficult to monitor/inspect under paragraph (f) of §63.1255 and a copy of the plan for monitoring or inspecting this equipment. [40 CFR §63.1255(g)(2)(vi)]
- x. A list of connectors removed from and added to the processes, as described in §63.174(i)(1), and documentation of the integrity of the weld for any removed connectors, as required in §63.174(j). This is not required unless the net credits for removed connectors is expected to be used. [40 CFR §63.1255(g)(2)(vii)]
- xi. For the equipment Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to monitor as provided under §63.178I, a list of equipment added to batch

product processes since the last monitoring period required in §63.178I(3)(ii) and (iii). This list must be completed for each type of equipment within 90 calendar days, or by the next Periodic Report, following the end of the monitoring period for the type of equipment monitored, whichever is later. Also, if Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to adjust monitoring frequency by the time in use, as provided in §63.178I(3)(iii), records demonstrating the proportion of the time during the calendar year the equipment is in use in a manner subject to the provisions of §63.1255 are required. Examples of suitable documentation are records of time in use for individual items of equipment or average time in use for the process unit. [40 CFR §63.1255(g)(2)(viii)]

- c. *Records of visual inspections* For visual inspections of equipment subject to the provisions of paragraphs I(2)(iii) and I(5)(iv) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall document that the inspection was conducted and the date of the inspection. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall maintain records as specified in paragraph (g)(4) of §63.1255 for leaking equipment identified in this inspection, except as provided in paragraph (g)(5) of §63.1255. These records shall be retained for 2 years. [40 CFR §63.1255(g)(3)]
- d. *Monitoring Records.* According to 40 CFR §63.1255(g)(4), when each leak is detected as specified in paragraph I of §63.1255, and paragraph (e) of §63.1255 and 63.169, and §§63.172 and 63.174, the following information shall be recorded and kept for 5 years (at least 2 years onsite, with the remaining 3 years either onsite or offsite):
  - i. The instrument and the equipment identification number and the operator name, initials, or identification number.
  - ii. The date the leak was detected and the date of the first attempt to repair the leak.
  - iii. The date of successful repair of the leak.
  - iv. The maximum instrument reading measured by Method 21 of 40 CFR part 60, appendix A, after the leak is successfully repaired or determined to be non-repairable.
  - v. “Repair delayed” and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak.
    - a) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall develop a written procedure that identifies the conditions that justify a delay of repair. The written procedures shall be included either as part of the startup/shutdown/malfunction plan, required by §63.1259(a)(3), or in

a separate document that is maintained at the plant site. Reasons for delay of repair may be documented by citing the relevant sections of the written procedure.

- b) If delay of repair was caused by depletion of stocked parts, there must be documentation that the spare parts were sufficiently stocked onsite before depletion and the reason for depletion.
- vi. If repairs were delayed, dates of process shutdowns that occur while the equipment is not repaired.
- vii. If the alternative in §63.174I(1)(ii) is not in use for the monitoring period, identification, either by list, location (area or grouping), or tagging of connectors disturbed since the last monitoring period required in §63.174(b), as described in §63.174(c)(1).
- viii. The date and results of follow-up monitoring as required in §63.174I(1)(i) and I(2)(ii). If identification of disturbed connectors is made by location, then all connectors within the designated location shall be monitored.
- ix. The date and results of the monitoring required in §63.178I(3)(i) for equipment added to a batch process since the last monitoring period required in §63.178I(3)(ii) and (iii). If no leaking equipment is found in this monitoring, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall record that the inspection was performed. Records of the actual monitoring results are not required.
- x. Copies of the periodic reports as specified in paragraph (h)(3) of §63.1255, if records are not maintained on a computerized data base capable of generating summary reports from the records.
- e. *Records of relief equipment compliance tests.* According to 40 CFR §63.1255(g)(6), and the dates and results of the monitoring following a pressure release for each pressure relief equipment subject to the provisions in §§63.165(a) and (b). The results shall include:
  - i. The background level measured during each compliance test.
  - ii. The maximum instrument reading measured at each piece of equipment during each compliance test.
- f. *Records for closed-vent systems.* According to 40 CFR §63.1255(g)(7), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall maintain records of the information specified in paragraphs (g)(7)(i) through (iii) of §63.1255 for closed-vent systems and control equipment subject to the provisions of paragraph (b)(4)(ii) of §63.1255. The

records specified in paragraph (g)(7)(i) of §63.1255 shall be retained for the life of the equipment. The records specified in paragraphs (g)(7)(ii) and (g)(7)(iii) of §63.1255 shall be retained for 2 years.

- i. The design specifications and performance demonstrations specified in paragraphs (g)(7)(i)(A) through (g)(7)(i)(D) of §63.1255.
  - a) Detailed schematics, design specifications of the control equipment, and piping and instrumentation diagrams.
  - b) The dates and specifications of any changes in the design specifications.
  - c) A description of the parameter or parameters monitored, as required in paragraph (b)(4)(ii) of §63.1255, to ensure that all control equipment is operated and maintained in conformance with their design and an explanation of why that parameter (or parameters) was selected for the monitoring.
- ii. *Records of exempt components.* Identification, either by list, location (area or group) of equipment in organic HAP service less than 300 hours per year subject to the provisions of §63.1255. [40 CFR §63.1255(g)(9)]
- iii. *Records of alternative means of compliance determination.* According to 40 CFR §63.1255(g)(10), owners and operators choosing to comply with the requirements of §63.179 shall maintain the following records:
  - a) Identification of the process(es) and the organic HAP they handle.
  - b) A schematic of the process, enclosure, and closed-vent system.
  - c) A description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control equipment.

*g. Reporting Requirements.*

- a. According to 40 CFR §63.1255(h)(1), each owner or operator subject to §63.1255 shall submit the reports listed in paragraphs (h)(1)(i) through (ii) of §63.1255.
  - i. A Notification of Compliance Status Report described in paragraph (h)(2) of §63.1255,
  - ii. Periodic reports described in paragraph (h)(3) of §63.1255.

- b. Notification of compliance status report.* According to 40 CFR §63.1255(h)(2), each owner or operator of a source subject to §63.1255 shall submit the information specified in paragraphs (h)(2)(i) through (iii) of §63.1255 in the Notification of Compliance Status Report described in §63.1260(f).
- i. The notification shall provide the information listed in paragraphs (h)(2)(i)(A) through (C) of §63.1255 for each process subject to the requirements of paragraphs (b) through (g) of §63.1255.
    - a) Process group identification.
    - b) Number of each equipment type (*e.g.*, valves, pumps) in organic HAP service, excluding equipment in vacuum service.
    - c) Method of compliance with the standard (for example, “monthly leak detection and repair” or “equipped with dual mechanical seals”)
  - ii. The notification shall provide the information listed in paragraphs (h)(2)(ii)(A) and (B) of §63.1255 for each process subject to the requirements of paragraph (b)(4)(iv) of §63.1255 and §63.178(b).
    - a) Products or product codes subject to the provisions of §63.1255, and
    - b) Planned schedule for pressure testing when equipment is configured for production of products subject to the provisions of §63.1255.
  - iii. The notification shall provide the information listed in paragraphs (h)(2)(iii)(A) and (B) of §63.1255 for each process subject to the requirements in §63.179.
    - a) Process identification.
    - b) A description of the system used to create a negative pressure in the enclosure and the control equipment used to comply with the requirements of paragraph (b)(4)(ii) of §63.1255.
  - iv. Any change in the information submitted under paragraph (h) of §63.1255 shall be provided to the Board and the EPA as part of subsequent Periodic Reports. Section 63.9(j) shall not apply to the

Notification of Compliance Status Report described in paragraph (h)(2) of §63.1255.

- c. *Periodic reports.* According to 40 CFR §63.1255(h)(3), the owner or operator of a source subject to §63.1255 shall submit Periodic Reports.
- i. A report containing the information in paragraphs (h)(3)(ii), (iii), and (iv) of §63.1255 shall be submitted semiannually. The first report shall be submitted no later than 240 days after the Notification of Compliance Status Report is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status Report is due. Each subsequent report shall cover the 6-month period following the preceding period.
  - ii. For equipment complying with the provisions of paragraphs (b) through (g) of §63.1255, except paragraph (b)(4)(iv) of §63.1255 and §63.179, the summary information listed in paragraphs (h)(3)(ii)(A) through (L) of §63.1255 for each monitoring period during the 6-month period.
    - a) The number of valves for which leaks were detected as described in paragraph (e)(3) of §63.1255, the percent leakers, and the total number of valves monitored;
    - b) Separately, the number of pumps and agitators for which leaks were detected as described in paragraph (c)(2) of §63.1255, the total number of pumps and agitators monitored, and the percent leakers.
    - c) Separately, the number of pumps and agitators for which leaks were not repaired as required in paragraph (c)(3) of §63.1255;
    - d) The number of connectors for which leaks were detected as described in §63.174(a), the percent of connectors leaking, and the total number of connectors monitored.
    - e) The number of connectors for which leaks were not repaired as required in §63.174(d), identifying the number of those that are determined non-repairable;
    - f) The facts that explain any delay of repairs and, where appropriate, why a process shutdown was technically infeasible.

- g) The results of all monitoring to show compliance with §§63.164(i), 63.165(a), and 63.172(f) conducted within the semiannual reporting period.
  - h) If applicable, the initiation of a monthly monitoring program under either paragraph I(4)(ii) or paragraph (e)(4)(i) of §63.1255.
  - i) If applicable, notification of a change in connector monitoring alternatives as described in §63.174I(1).
- iii. Any revisions to items reported in earlier Notification of Compliance Status report, if the method of compliance has changed since the last report.

*d. Monitoring Requirements*

- a. *Emissions averaging.* According to §63.1258(f), the owner or operator of any affected source that chooses to comply with the requirements of §63.1252(d) shall meet all monitoring requirements specified in paragraphs (b)(1) and (3) of §63.1258, as applicable, for all processes and storage tanks included in the emissions averaging. [40 CFR §63.1258]

*e. Reporting Requirements*

- a. *Reports of Leak Detection and Repair (LDAR) programs.* According to §63.1260(j), the owner or operator of any affected source implementing the LDAR program specified in §63.1255 of subpart GGG shall implement the reporting requirements in §63.1255 of subpart GGG. Copies of all reports shall be retained as records for a period of 5 years, in accordance with the requirements of §63.10(b)(1), as follows:
  - i. According to 40 CFR §63.10(b)(1) part 63, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall maintain files of all information (including all reports and notifications) required by part 63 recorded in a form suitable and readily available for expeditious inspection and review. The files shall be retained for at least 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record. At a minimum, the most recent 2 years of data shall be retained on site. The remaining 3 years of data may be retained off site. Such files may be maintained on microfilm, on a computer, on computer floppy disks, on magnetic tape disks, or on microfiche. [40 CFR §63.10(b)(1)]

## F. Test Methods

1. Except as specified in paragraph (a)(5) of §63.1257, the procedures specified in paragraphs (c), (d), (e), and (f) of §63.1257 are required to demonstrate initial compliance with §§63.1253, 63.1254, 63.1256, and 63.1252(e), respectively. The provisions in paragraphs (a) (2) through (3) apply to performance tests that are specified in paragraphs (c), (d), and (e) of §63.1257. The provisions in paragraph (a)(5) of this section are used to demonstrate initial compliance with the alternative standards specified in §§63.1253(d) and 63.1254(c). The provisions in paragraph (a)(6) of §63.1257 are used to comply with the outlet concentration requirements specified in §§63.1253(c), 63.1254 (a)(2)(i) and (a)(3)(ii)(B), 63.1254(b)(i) and 63.1256(h)(2). [40 CFR §63.1257(a)]
2. To demonstrate that the control equipment meets the required control efficiency, a design evaluation must address the composition and organic HAP concentration of the vent stream entering the control equipment. A design evaluation also must address other vent stream characteristics and control equipment operating parameters *as specified in any one of paragraphs (a)(1) (i) through (vi) of §63.1257, depending on the type of control equipment that is used.* If the vent stream is not the only inlet to the control equipment, the efficiency demonstration also must consider all other vapors, gases, and liquids, other than fuels, received by the control equipment. [40 CFR §63.1257(a)(1)]
3. An owner or operator using *any control equipment specified in paragraphs (a)(4)(i) through (iv) of §63.1257* is exempt from the initial compliance provisions in paragraphs (c), (d), and (e) of §63.1257. [40 CFR §63.1257(a)(4)]
4. When testing is conducted to measure emissions from an affected source, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall use the test methods specified in paragraphs (b)(1) through (10) of §63.1257. [40 CFR §63.1257(b)]
5. An owner or operator with two or more affected storage tanks may demonstrate compliance with §63.1253, as applicable, by fulfilling the requirements of paragraphs (g)(1) through (4) of §63.1257. [40 CFR §63.1257(g)]
6. An owner or operator with two or more affected processes complying with §63.1254 by using emissions averaging shall demonstrate compliance with paragraphs (h)(1), (2) and (3) of §63.1257. [40 CFR §63.1257(h)]
7. The overall percent reduction efficiency shall be calculated using Equation 62 of subpart GGG. [40 CFR §63.1257(h)(4)]