

Pfizer Pharmaceuticals LLC (CRUCE DAVILA) to achieve emission levels that would be required by the applicable standard at other times if this is not consistent with safety and good air pollution control practices, nor does it require Pfizer Pharmaceuticals LLC (CRUCE DAVILA) to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Board and the EPA which may include, but is not limited to, sampling results, review of operation and maintenance procedures (including the malfunction, startup, and shutdown plan required in paragraph (e)(3) of §63.2.), review of operation and maintenance records, and inspection of the source. [40 CFR, §63.6(e)(1)(i)]

2. Malfunctions must be corrected as soon as practicable after their occurrence in accordance with the malfunction, startup, and shutdown plan required in paragraph (e)(3) of §63.6 of 40 CFR. To the extent that an unexpected event arises during a malfunction, startup, or shutdown, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply by minimizing emissions during such a malfunction, startup, or shutdown event consistent with safety and good air pollution control practices. [40 CFR, §63.6(e)(1)(ii)]
 - i. Operation and maintenance requirements established pursuant to section 112 of the Act are enforceable independent of emissions limitations or other requirements in relevant standards.³ [40 CFR, §63.6(e)(1)(iii)]
 - ii. Malfunction, startup, and shutdown plan. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must develop and implement a written malfunction, startup, and shutdown plan that describe, in detail, procedures for operating and maintaining the source during periods of malfunction, startup, and shutdown, and a program of corrective action for malfunctioning process and air pollution control and monitoring equipment used to comply with the relevant standard. This plan must be developed by the source's compliance date for that relevant standard. [40 CFR, §63.6(e)(3)(i)]
 - iii. During periods of startup, shutdown, and malfunction, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) operates and maintains each affected source, (including associated air pollution control and monitoring equipment) in

³ According to §63.2 of 40 CFR, relevant standards mean an emission standard, an alternative emission standard, an alternative emission limitation, or an equivalent emission limitation established pursuant to section 112 of the Act that applies to the stationary source, the group of stationary sources or the portion of the stationary source regulated by said standard or limitation. A relevant standard may include or consist of a design, equipment, work practice, or operational requirement, or other measure, process, method, system, or technique (including prohibition of emissions) that the EPA (or a State) establishes for new or existing sources to which such standard or limitation applies. Every relevant standard established pursuant to section 112 of the Act includes subpart A of part 63 and all applicable appendices of part 63 or of other parts of chapter 1 that are referenced in that standard.

accordance with the procedures specified in the malfunction, startup, and shutdown plan developed under paragraph (e)(3)(i) of §63.6. [40 CFR, §63.6(e)(3)(ii)]

- iv. When actions taken by Pfizer Pharmaceuticals LLC (CRUCE DAVILA) during a malfunction, startup, or shutdown (including actions taken to correct a malfunction) are consistent with the procedures specified in the affected source's malfunction, startup, and shutdown plan, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must keep records for that event which demonstrate that the procedures specified in the plan were followed. These records may take the form of a "checklist," or other effective form of recordkeeping that confirms conformance with the malfunction, startup, and shutdown plan for that event. In addition, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must keep records of these events as specified in §63.10(b), including records of the occurrence and duration of each malfunction, startup, or shutdown of operation and each malfunction of the air pollution control and monitoring equipment. Furthermore, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall confirm that actions taken during the relevant reporting period during periods of malfunction, startup, and shutdown were consistent with the affected source's startup, shutdown and malfunction plan in the semiannual (or more frequent) malfunction, startup, and shutdown report required in §63.10(d)(5). [40 CFR, §63.6(e)(3)(iii)]
- v. If an action taken by Pfizer Pharmaceuticals LLC (CRUCE DAVILA) during a malfunction, startup, or shutdown (including an action taken to correct a malfunction) is not consistent with the procedures specified in the affected source's malfunction, startup, and shutdown plan, and the source exceeds any applicable emission limitation in the relevant emission standard, then Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must record the actions taken for that event and must report such actions by means of a telephone call or fax to EQB and EPA within 2 working days after commencing actions inconsistent with the plan, followed by a letter within 7 working days after the end of the event, in accordance with §63.10(d)(5) (unless Pfizer Pharmaceuticals LLC (CRUCE DAVILA) makes alternative reporting arrangements, in advance, with the Board and the EPA). [40 CFR, §63.6(e)(3)(iv)]
- vi. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must maintain a written copy of the malfunction, startup, and shutdown plan on file and must make the plan available to the Board or the EPA, upon request, for inspection, for the life of the affected source or until the affected source is no longer subject to the provisions of part 63. In addition, if the malfunction, startup, and shutdown plan is subsequently revised, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must maintain on file each previous (i.e., superseded) version of the malfunction, startup, and shutdown plan, and must make each such previous version available for inspection at the request of the Board or the

EPA for a period of 5 years after revision of the plan. If at any time after adoption of a malfunction, startup, and shutdown plan the affected source ceases operation or is otherwise no longer subject to the provisions of part 63, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must retain a copy of the most recent plan for 5 years from the date the source ceases operation or is no longer subject to part 63 and must make the plan available upon request for inspection and copying by the Board or the EPA. The Board or the EPA may at any time request in writing that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) submit a copy of any malfunction, startup, and shutdown plan (or a portion thereof) which is maintained at the affected source or in the possession of Pfizer Pharmaceuticals LLC (CRUCE DAVILA). Upon receipt of such a request, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must promptly submit a copy of the requested plan (or a portion thereof) to the Board and the EPA. The Board or the EPA may request that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) submit a particular malfunction, startup, or shutdown plan (or a portion thereof) whenever a member of the public submits a specific and reasonable request to examine or to receive a copy of that plan or portion of a plan. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to submit the required copy of any malfunction, startup, and shutdown plan to the Board and the EPA in an electronic format. If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) claims that any portion of such a malfunction, startup, and shutdown plan is confidential business information entitled to protection from disclosure under section 114I of the Act or 40 CFR 2.301, the material which is claimed as confidential must be clearly designated in the submission. [40 CFR, §63.6(e)(3)(v)]

- vii. To satisfy the requirements of §63.6 to develop a malfunction, startup, and shutdown plan, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may use the affected source's standard operating procedures (SOP) manual, or an Occupational Safety and Health Administration (OSHA) or other plan, provided the alternative plans meet all the requirements of §63.6 and are made available for inspection or submitted when requested by the Board or the EPA. [40 CFR, §63.6(e)(3)(vi)]
- viii. According to 40 CFR, §63.6(e)(3)(vii) and based on the results of a determination made under paragraph (e)(1)(i) of §63.6, the Board or the EPA may require that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) make changes to the malfunction, startup, and shutdown plan for that source. The Board or the EPA must require appropriate revisions to a malfunction, startup, and shutdown plan, if the Board or the EPA finds that the plan:
 - a. Does not address a malfunction, startup, or shutdown event that has occurred;

- b. Fails to provide for the operation of the source (including associated air pollution control and monitoring equipment) during a malfunction, startup, or shutdown event in a manner consistent with the general duty to minimize emissions established by paragraph (e)(1)(i) of §63.6;
 - c. Does not provide adequate procedures for correcting malfunctioning process and/or air pollution control and monitoring equipment as quickly as practicable; or
 - d. Includes an event that does not meet the definition of malfunction, startup, or shutdown listed in §63.2.
3. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) will periodically revise the malfunction, startup, and shutdown plan for the affected source as necessary to satisfy the requirements of part 63 to reflect changes in equipment or procedures at the affected source. Unless the Board or the EPA provides otherwise, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must make such revisions to the malfunction, startup, and shutdown plan without prior approval by the Board or the EPA. However, each such revision to a malfunction, startup, and shutdown plan must be reported in the semiannual report required by §63.10(d)(5). If the malfunction, startup, and shutdown plan fails to address or inadequately addresses an event that meets the characteristics of a malfunction but was not included in the malfunction, startup, and shutdown plan at the time Pfizer Pharmaceuticals LLC (CRUCE DAVILA) developed the plan, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must revise the malfunction, startup, and shutdown plan within 45 days after the event to include detailed procedures for operating and maintaining the source during similar malfunction events and a program of corrective action for similar malfunctions of process or air pollution control and monitoring equipment. In the event that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) makes any revision to the malfunction, startup, and shutdown plan which alters the scope of the activities at the source which are deemed to be a malfunction, startup, or shutdown, or otherwise modifies the applicability of any emission limit, work practice requirement, or other requirement in a standard established under part 63, the revised plan shall not take effect until after Pfizer Pharmaceuticals LLC (CRUCE DAVILA) provides a written notice describing the revision to the Board and the EPA. [40 CFR, §63.6(e)(3)(viii)]
4. This title V permit requires that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) adopt a malfunction, startup, and shutdown plan which conforms to the provisions of part 63 of 40 CFR and that it operate and maintain the source in accordance with the procedures specified in the current malfunction, startup, and shutdown plan. However, any revisions made to the malfunction, startup, and shutdown plan in accordance with the procedures established by part 63 shall not be deemed to constitute permit revisions under part 70 or part 71 of Chapter I of 40 CFR. Moreover, none of the procedures specified by the malfunction, startup, and

shutdown plan for an affected source shall be deemed to fall within the permit shield provision in section 504(f) of the Act. [40 CFR, §63.6(e)(3)(ix)]

SECTION VIII – NATIONAL EMISSION STANDARDS FOR THE PHARMACEUTICAL INDUSTRY – CHEMICAL PLANT (EU-2)

A. Applicability

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply with the provisions of 40 CFR part 63 subpart A contained in Table 1 of subpart GGG. [§63.1250I]
2. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must follow the procedures specified in §63.1250(e)(1)-(5) to determine to which PMPU a storage tank shall belong.
3. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must be in compliance with the National Emission Standards for Pharmaceuticals Production contained in 40 CFR part 63 subpart GGG for October 21, 2002, according to §63.1250(f).
4. All the provisions set forth in subpart GGG shall apply at all times except that emission limitations shall not apply during periods of: startup; shutdown; and malfunction, if this precludes the ability of a particular emission point of an affected source to comply with one or more specific emission limitations to which it is subject and Pfizer Pharmaceuticals LLC (CRUCE DAVILA) follows the provisions for periods of malfunction, startup, and shutdown, as specified in §§63.1259(a)(3) and 63.1260(i). [40 CFR §63.1250(g)(1)]
5. All the provisions of §63.1255 of subpart GGG shall apply at all times except during periods of non-operation of the PMPU (or specific portion thereof) in which the lines are drained and depressurized resulting in the cessation of the emissions to which §63.1255 applies. [40 CFR §63.1250(g)(2)]
6. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall not shut down items of equipment that are required or utilized for compliance with the emissions limitations of subpart GGG during times when emissions (or, where applicable, wastewater streams or residuals) are being routed to such items of equipment, if the shutdown would contravene emissions limitations of this subpart applicable to such items of equipment. This premise does not apply if the item of equipment is malfunctioning, or if Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must shut down the equipment to avoid damage due to a malfunction of the PMPU or portion thereof. [40 CFR §63.1250(g)(3)]

7. During startups, shutdowns, and malfunctions when the emissions limitations of this subpart do not apply pursuant to paragraphs (g)(1) through (3), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall implement, to the extent reasonably possible, measures to prevent or minimize excess emissions to the extent practical. The measures to be taken shall be identified in the applicable malfunction, startup, and shutdown plan, and may include, but are not limited to, air pollution control technologies, work practices, pollution prevention, sampling, and/or changes in the manner of operation of the source. Back-up control equipment are not required, but may be used if available. [40 CFR §63.1250(g)(4)]
8. After the compliance dates specified in §63.1250(f), a facility subject to the provisions of subpart GGG that is also subject to the provisions of any other subpart of part 63 may elect with which of the subparts to comply as to the maintenance of records and reporting to EPA. [40 CFR §6312.50(h)(1)(i)]
9. After the compliance dates specified in paragraph (f) of §63.1250(f), an offsite reloading or cleaning facility subject to §63.1253(f) shall be deemed to be in compliance with the provisions of §63.1253(f)(7)(ii) or (iii) if it complies with the emission standards and initial compliance, sampling, recordkeeping, and reporting provisions associated to any other subpart of part 63. [40 CFR §6312.50(h)(1)(ii)]
10. After the compliance dates specified in §63.1250(f), if any control equipment subject to this subpart is also subject to monitoring, recordkeeping, and reporting requirements in 40 CFR part 264, subpart AA, BB, or CC, or is subject to sampling and recordkeeping requirements in 40 CFR part 265, subpart AA, BB, or CC, and Pfizer Pharmaceuticals LLC (CRUCE DAVILA) complies with the periodic reporting requirements under 40 CFR part 264, subpart AA, BB, or CC that would apply to the equipment if the facility had final-permitted status, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to comply either with the monitoring, recordkeeping, and reporting requirements of subpart GGG, or with parts 264 and/or 265, as described in §63.1250(h)(2)(i), which shall constitute compliance with the monitoring, recordkeeping, and reporting requirements of subpart GGG. If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to comply with the provisions of parts 264 and/or 265, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall report all information required by §63.1260(g) and (i). Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall identify in the Notification of Compliance Status, required by §63.1260(f), the monitoring, recordkeeping, and reporting authority under which Pfizer Pharmaceuticals LLC (CRUCE DAVILA) will comply. [40 CFR §63.1250(h)(2)(i)]
11. After the compliance dates specified in §63.1250(f), if any equipment at an affected source that is subject to §63.1255, is also subject to 40 CFR part 264, subpart BB, or to 40 CFR part 265, subpart BB, then compliance with the

recordkeeping and reporting requirements of 40 CFR parts 264 and/or 265 may be used to comply with the recordkeeping and reporting requirements of §63.1255, to the extent that the requirements of 40 CFR parts 264 and/or 265 duplicate the requirements of §63.1255. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall identify in the Notification of Compliance Status, required by §63.1260(f), if it will comply with the recordkeeping and reporting authority under 40 CFR parts 264 and/or 265. [40 CFR §63.1250(h)(2)(ii)]

12. After the compliance dates specified in §63.1250(f), a storage tank controlled with a floating roof and in compliance with the provisions of 40 CFR 60.112b, subpart Kb, constitutes compliance with the provisions of subpart GGG. A storage tank with a fixed roof, closed vent system, and control equipment in compliance with the provisions of 40 CFR 60.112b, subpart Kb must comply with the sampling, recordkeeping, and reporting provisions of subpart GGG. [40 CFR §63.1250(h)(3)]
13. After the compliance dates specified in §63.1250(f), an affected source with equipment subject to subpart I of part 63 may elect to comply with either the provisions of §63.1255 or the provisions of subpart H of part 63 for all such equipment. [40 CFR §63.1250(h)(4)]
14. After the compliance dates specified in §63.1250(f), the owner or operator of affected wastewater that is also subject to provisions in 40 CFR parts 260 through 272 may elect to determine whether part 63 subpart GGG or parts 260 through 272 contain the more stringent control, testing, sampling, recordkeeping, and reporting requirements. Compliance with provisions of 40 CFR parts 260 through 272 that are determined to be more stringent than the requirements of subpart GGG constitutes compliance with this subpart. [40 CFR §63.1250(h)(5)]
15. After the compliance dates specified in §63.1250(f), an affected source with equipment in a PMPU that is also part of an affected source under subpart PPP of part 63 may elect to demonstrate compliance with §63.1254 by controlling all process vents in accordance with §63.1425 (b), (c)(1), (c)(3), (d), and/or (f). Alternatively, the owner or operator may elect to determine which process vents must be controlled to comply with the percent reduction requirements of §63.1254 and control only those vents in accordance with §63.1425 (b), (c)(1), (c)(3), (d), and/or (f). For any PMPU controlled in accordance with the requirements of §63.1425, the owner or operator must also comply with all other requirements in subpart PPP. [40 CFR §63.1250(h)(6)]

B. General

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall control Hazardous Air Pollutants (HAP) emissions to the level specified in §63.1252 on and after the

compliance dates specified in §63.1250(f). Continuous compliance shall be demonstrated in accordance with the provisions of §63.1258. [40 CFR §63.1252]

- a. 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. [40 CFR §63.1252(a)].
- b. The owner or operator of a closed-vent system that contains bypass lines that could divert a vent stream away from a control equipment used to comply with the requirements in §§63.1253, and 63.1254 shall comply with the requirements of Table 4 to subpart GGG and one of the following alternatives:
 - i. 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 equipment to the atmosphere. [40 CFR §63.1252(b)(1)].
 - ii. 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). [40 CFR §63.1252(b)(2)]
- c. Except as provided in paragraph I(2) of §63.1252, owners and operators of affected sources shall comply with the requirements in paragraph I(1) of this section for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations. [40 CFR §63.1252I]
 - i. The heat exchange system shall be treated according to the provisions of §63.104, except that the sampling frequency shall be no less than quarterly. [40 CFR §63.1252I(1)]
 - ii. 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. [40 CFR §63.1252I(2)]

- d. Except as specified in paragraphs (d)(1) through (5) of §63.1252, 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 [40 CFR §63.1252(d)]
 - i. Not more than 20 processes subject to §63.1254(a)(1)(i), and 20 storage tanks subject to §63.1253(b)(1) or (c)(1)(i) at an affected source may be included in an emissions averaging group. [40 CFR §63.1252(d)(6)]
 - ii. Compliance with the emission standards in §63.1253 shall be satisfied when the annual percent reduction efficiency is greater than or equal to 90 percent for those tanks meeting the criteria of §63.1253(a)(1) and 95 percent for those tanks meeting the criteria of §63.1253(a)(2), as demonstrated using the test methods and compliance procedures specified in §63.1257(g). [40 CFR §63.1252(d)(7)]
 - iii. Compliance with the emission standards in §63.1254(a)(1)(i) shall be satisfied when the annual percent reduction efficiency is greater than or equal to 93 percent, as demonstrated using the test methods and compliance procedures specified in §63.1257(h). [40 CFR §63.1252(d)(8)]
- e. Except as provided in paragraph (e)(1) of §63.1252, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may choose to meet the pollution prevention alternative requirement specified in either paragraph (e)(2) or (3) of this section for any PMPU or for any situation described in paragraph (e)(4) of this section, in lieu of the requirements specified in §§63.1253, 63.1254, 63.1255, and 63.1256. [40 CFR §63.1252(e)]
- f. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the provisions of Table 5 of subpart GGG, for each item of equipment meeting all the criteria specified in paragraphs (f)(2) through (4) and either paragraph (f)(5)(i) or (ii) of §63.1252. [40 CFR §63.1252(f)]
- g. If a combustion equipment is used to comply with the provisions of §§63.1253, 63.1254, 63.1256(h) for a halogenated vent stream, then the vent stream shall be sent to a halogen reduction equipment such as, but not limited to, a scrubber, before it is discharged to the atmosphere. The halogen reduction equipment must reduce emissions by the amounts specified in one of the following: [40 CFR §63.1252(g)]
 - i. A halogen reduction equipment after the combustion control equipment must reduce overall emissions of hydrogen halides and halogens, as defined

in §63.1251, by 95 percent or to a concentration less than or equal to 20 ppmv. [40 CFR §63.1252(g)(1)]

- ii. A halogen reduction equipment located before the combustion control equipment must reduce the halogen atom content of the vent stream to a concentration less than or equal to 20 ppmv. [40 CFR §63.1252(g)(2)]

C. Storage Tanks

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply with the requirements of §63.1253(b) for the methanol tank and for every tank whose design capacity is equal or greater than 10,000 gallons but less than 20,000 gallons storing a liquid for which the maximum true steam pressure of total HAP is greater than or equal to 1.9 psia. [40 CFR §63.1253(a)(1)]
2. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall equip the methanol storage tank and any other affected storage tank with one of the following alternatives a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of §63.1252(b) with a control equipment that meets any of the following conditions. [40 CFR §63.1253(b)]:
 - a. Reduces inlet emissions of total HAP by 90 percent by weight or greater;
 - b. Reduces emissions to outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;
 - c. Is an enclosed combustion equipment that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760 °C;
 - d. Is a flare that meets the requirements of §63.11(b); or
 - e. Is a control equipment specified in §63.1257(a)(4).
3. The owner or operator of a tank with design capacity equal or greater than 20,000 gallons storing a liquid for which the maximum true steam pressure of total HAP is greater than or equal to 1.9 psia must comply with the requirements of §63.1253I. [40 CFR §63.1253(a)(2)]
4. Alternate standard – (To comply with the standard of §63.1253 one of the following alternatives may be used.)
 - a. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall route storage tank vents to a:

- i. Combustion control equipment achieving an outlet IOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less.
 - ii. Non-combustion control equipment, achieving an outlet IOC concentration, as calibrated on methane or the predominant HAP, of 50 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 50 ppmv or less. [40 CFR §63.1253(d)]
5. The specifications and requirements in paragraphs (b) through (d) of §63.1253 for control equipment do not apply during periods of planned routine maintenance. Periods of scheduled routine maintenance of the control equipment (including centralized combustion control equipment subject to §63.1252(h)), during which the control equipment does not meet the specifications of paragraphs (b) through (d) of §63.1253, as applicable, shall not exceed 240 hours in any 365-day period. [40 CFR §63.1253(e)]
6. As an alternative to complying with the requirements in paragraphs (b) and (c) of §63.1253, Pfizer Pharmaceuticals LLC (CRUCE DAVILA), may implement vapor balancing in accordance with paragraphs (f)(1) through (7) of this same section. [40 CFR §63.1253(f)]

D. Process Vents

1. Existing Sources – For each process, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply with the requirements in paragraphs (a)(1) and (3) of §63.1254. [40 CFR §63.1254]
2. New Sources
 - a. Except as provided in paragraph (b)(2) of §63.1254, uncontrolled HAP emissions from the sum of all process vents within a process at a new affected source shall be reduced by 98 percent or greater by weight or controlled in accordance with any of requirements of paragraphs (a)(1)(ii)(A) through (D) of §63.1254. [40 CFR §63.1254(b)(1)]
 - b. The actual HAP emissions from the sum of all process vents for which Pfizer Pharmaceuticals LLC (CRUCE DAVILA) is not complying with the above requirement are limited to 900 kg in any 365-day period. [40 CFR §63.1254(b)(2)]
3. Process-based emission reduction requirement

- a. Uncontrolled HAP emissions from the sum of all process vents within a process that are not subject to the requirements of paragraph (a)(3) of §63.1254 shall be reduced by 93 percent or greater by weight, as specified in paragraph (a)(1)(ii) of §63.1254. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall notify of changes in the compliance method according to the procedures in §63.1260(h). [40 CFR §63.1254(a)(1)(i)]
 - b. Any one or more vents within a process must be controlled in accordance with any of the procedures in paragraphs (a)(1)(ii)(A) through (D):
 - i. Outlet concentrations shall be less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;
 - ii. By a flare that meets the requirements of §63.11(b);
 - iii. By a control equipment specified in §63.1257(a)(4); or
 - iv. In accordance with the alternative standard specified in paragraph (c) of §63.1254. [40 CFR §63.1254(a)(1)(ii)]
4. For New and Existing Sources – *Alternative Standard – (To comply with the standard for this section one of the following alternatives may be used)*
- a. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall rout the vents from a process to a to a non-combustion control equipment achieving an outlet IOC concentration, as calibrated on methane or the predominant HAP, of 50 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 50 ppmv or less. [40 CFR §63.1254I]

E. Standards for equipment leaks

1. General Equipment Leak Requirements

- a. The provisions of 40 CFR §63.1255 apply to pumps, compressors, agitators, pressure relief equipment, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control equipment, and closed-vent systems required by 40 CFR part 63, subpart GGG that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year within a source subject to the provisions of 40 CFR part 63, subpart GGG. [40 CFR §63.1255(a)(1)]
- b. Consistency with other regulations. After the compliance date for a process, equipment subject to §63.1255 and any of the sections of 40 CFR parts 60 or 61 shall be required to comply only with the provisions of 40 CFR part 63, subpart GGG. [40 CFR §63.1255(a)(2)]

- c. The provisions in §63.1(a)(3) of subpart A of part 63 do not alter the provisions in paragraph (a)(2) of §63.1255. [40 CFR §63.1255(a)(4)]
- d. Lines and equipment not containing process fluids are not subject to the provisions of §63.1255. Utilities, and other non-process lines, such as heating and cooling systems which do not combine their materials with those in the processes they serve, are not considered to be part of a process. [40 CFR §63.1255(a)(5)]
- e. The provisions of §63.1255 do not apply to bench-scale⁴ processes, regardless of whether the processes are located at the same plant site as a process subject to the provisions of 40 CFR part 63, subpart GGG. [40 CFR §63.1255(a)(6)]
- f. Equipment to which §63.1255 applies shall be identified such that it can be distinguished readily from equipment that is not subject to §63.1255. Identification of the equipment does not require physical tagging of the equipment. For example, the equipment may be identified on a plant site plan, in log entries, or by designation of process boundaries by some form of weatherproof identification. If changes are made to the affected source subject to the leak detection requirements, equipment identification for each type of component shall be updated, if needed, within 90 calendar days or by the next Periodic Report following the end of the monitoring period for that component, whichever is later. [40 CFR §63.1255(a)(7)]
- g. Equipment that is in vacuum service is excluded from the requirements of §63.1255. [40 CFR §63.1255(a)(8)]
- h. Equipment that is in organic HAP service, but is in such service less than 300 hours per calendar year, is excluded from the requirements of §63.1255 if it is identified as required in paragraph (g)(9) of §63.1255. [40 CFR §63.1255(a)(9)]
- i. According to 40 CFR §63.1255(a)(10), when each leak is detected by visual, audible, or olfactory means, or by monitoring as described in §63.180(b) or (c), the following requirements apply:
 - i. A weatherproof and readily visible identification, marked with the equipment identification number, shall be attached to the leaking equipment.
 - ii. The identification on a valve in light liquid or gas/vapor service may be removed after it has been monitored as specified in paragraph (e)(7)(iii) of §63.1255, and no leak has been detected during the follow-up monitoring.

⁴ *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. [40 CFR §63.1251]

- iii. The identification on equipment, except on a valve in light liquid or gas/vapor service, may be removed after it has been repaired.
- j. Except as provided in paragraph (a)(11)(i) of §63.1255, all terms in subpart GGG that define a period of time for completion of required tasks (*e.g.*, weekly, monthly, quarterly, annual) refer to the standard calendar periods unless specified otherwise in the section or paragraph that imposes the requirement. [40 CFR §63.1255(a)(11)]
- i. If the initial compliance date does not coincide with the beginning of the standard calendar period, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to utilize a period beginning on the compliance date, or may elect to comply in accordance with the provisions of paragraph (a)(11)(ii) or (iii) of §63.1255.
 - ii. Time periods specified in subpart GGG for completion of required tasks may be changed by mutual agreement between Pfizer Pharmaceuticals LLC (CRUCE DAVILA) and the Board and the EPA, as specified in subpart A of part 63. For each time period that is changed by agreement, the revised period shall remain in effect until it is changed. A new request is not necessary for each recurring period.
 - iii. Except as provided in paragraph (a)(11)(i) or (ii) of §63.1255, where the period specified for compliance is a standard calendar period, if the initial compliance date does not coincide with the beginning of the calendar period, compliance shall be required according to the schedule specified in paragraph (a)(11)(iii)(A) or (B) of §63.1255, as appropriate.
 - a) Compliance shall be required before the end of the standard calendar period within which the initial compliance date occurs if there remain at least 3 days for tasks that must be performed weekly, at least 2 weeks for tasks that must be performed monthly, at least 1 month for tasks that must be performed each quarter, or at least 3 months for tasks that must be performed annually; or
 - b) In all other cases, compliance shall be required before the end of the first full standard calendar period after the period within which the initial compliance date occurs.
 - iv. In all instances where a provision of subpart GGG requires completion of a task during each of multiple successive periods, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall perform the required task at any time during each period, provided the task is conducted at a reasonable interval after completion of the task during the previous period.

k. In all cases where the provisions of subpart GGG require an owner or operator to repair leaks by a specified time after the leak is detected, it is a violation of §63.1255 to fail to take action to repair the leaks within the specified time. If action is taken to repair the leaks within the specified time, failure of that action to successfully repair the leak is not a violation of §63.1255. However, if the repairs are unsuccessful, and a leak is detected the owner or operator shall take further action as required by applicable provisions of §63.1255. [40 CFR §63.1255(a)(12)]

2. References.

a. The owner or operator of a source subject to §63.1255 shall comply with the provisions of subpart H of part 63, as specified in paragraphs (b)(2) through (4) of §63.1255. The term "process unit" as used in subpart H of part 63 shall be considered to mean the same as "group of processes" for sources subject to subpart GGG. The term "fuel gas system," as used in subpart H of part 63, shall not apply for the purposes of subpart GGG. [40 CFR §63.1255(b)(1)]

b. Sections 63.160, 63.161, 63.162, 63.163, 63.167, 63.168, 63.170, 63.173, 63.175, 63.176, 63.181, and 63.182 shall not apply for the purposes of subpart GGG. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the provisions specified in paragraphs (b)(2)(i) through (viii) of §63.1255. [40 CFR §63.1255(b)(2)]

i. Sections 63.160 and 63.162 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (a) of §63.1255;

ii. Section 63.161 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with §63.1251;

iii. Sections 63.163 and 63.173 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph I of §63.1255;

iv. Section 63.167 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (d) of §63.1255;

v. Section 63.168 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (e) of §63.1255;

vi. Section 63.170 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with §63.1254;

vii. Section 63.181 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (g) of §63.1255; and

viii. Section 63.182 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (h) of §63.1255.

- c. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with §§63.165, 63.166, 63.169, 63.177, and 63.179 in their entirety, except that when these sections reference other sections of subpart H of part 63, references shall mean the sections specified in paragraphs (b)(2) and (4) of §63.1255. Section 63.165 applies to pressure relief equipment in gas/vapor service. Section 63.166 applies to sampling connection systems. In respect to Pfizer Pharmaceuticals LLC (CRUCE DAVILA), section 63.169 applies to instrumentation systems; and pressure relief equipment in liquid service. Section 63.177 applies to general alternative means of emission limitation. Section 63.179 applies to alternative means of emission limitation for enclosed-vented process units. [40 CFR §63.1255(b)(3)]
- d. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with §§63.171, 63.172, 63.174, 63.178, and 63.180, except as specified in paragraphs (b)(4)(i) through (vi) of §63.1255. [40 CFR §63.1255(b)(4)]
- i. Section 63.171 shall apply, except §63.171(a) shall not apply. Instead, delay of repair of equipment for which leaks have been detected is allowed if one of the conditions in paragraphs (b)(4)(i)(A) through (B) exists:
- a. The repair is technically infeasible without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown. [40 CFR §63.1255(b)(4)(i)(A)]
- b. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) determines that repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown. [40 CFR §63.1255(b)(4)(i)(B)]
- ii. Section 63.172 shall apply for closed-vent systems used to comply with §63.1255, and for control equipment used to comply with §63.1255 only, except:
- a) Section 63.172(k) and (l) shall not apply. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall instead comply with paragraph (f) of §63.1255. [40 CFR §63.1255(b)(4)(ii)(A)]
- b) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may, instead of complying with the provisions of §63.172(f), design a closed-vent system to operate at a pressure below atmospheric pressure. The system shall be equipped with at least one pressure gauge or other pressure measurement equipment that can be read from a readily accessible location to verify that negative pressure is being maintained in the closed-vent system when the associated control equipment is operating. [40 CFR §63.1255(b)(4)(ii)(B)]

- c) The requirements apply at all times, except as specified in §63.1250(g). Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may not comply with the planned routine maintenance provisions in §63.1252(h). [40 CFR §63.1255(b)(4)(ii)(C)]
- iii. Section 63.174 shall apply except:
- a) Sections 63.174(f), (g), and (h) shall not apply. Instead of §63.174(f), (g), and (h), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (f) of §63.1255. Section 63.174(b)(3) shall not apply. Instead of §63.174(b)(3), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraphs (b)(4)(iii)(B) through (F) of §63.1255. [40 CFR §63.1255(b)(4)(iii)(A)]
 - b) If the percent leaking connectors in a group of processes was greater than or equal to 0.5 percent during the initial monitoring period, monitoring shall be performed once per year until the percent leaking connectors is less than 0.5 percent. [40 CFR §63.1255(b)(4)(iii)(B)]
 - c) If the percent leaking connectors was less than 0.5 percent, but equal to or greater than 0.25 percent, during the initial or last required monitoring period, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to monitor once every 4 years. An owner or operator may comply with the requirements of paragraph (b)(4)(iii)(C) of §63.1255 by monitoring at least 40 percent of the connectors in the first 2 years and the remainder of the connectors within the next 2 years. The percent leaking connectors will be calculated for the total of all required monitoring performed during the 4-year period. [40 CFR §63.1255(b)(4)(iii)(C)]
 - d) Except as provided in paragraph (b)(4)(iii)(B) of §63.1255, if leaking connectors comprise at least 0.5 percent but less than 1.0 percent of the connectors during the last monitoring period, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor at least once every 2 years for the next monitoring period. At the end of that 2-year monitoring period, if the percent leaking connectors is greater than or equal to 0.5 percent, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor once per year until the percent leaking connectors is less than 0.5 percent. If, at the end of a monitoring period, the percent leaking connectors is less than 0.5 percent, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor in accordance with paragraph (b)(4)(iii)(C) or (F) of §63.1255, as appropriate. [40 CFR §63.1255(b)(4)(iii)(D)]

- e) If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) determines that 1 percent or greater of the connectors in a group of processes are leaking, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor the connectors once per year. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to use the provisions of paragraph (b)(4)(iii)(C), (D), or (F) of §63.1255, as appropriate, after a monitoring period in which less than 1 percent of the connectors are determined to be leaking. [40 CFR §63.1255(b)(4)(iii)(E)]
 - f) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to perform monitoring once every 8 years if the percent leaking connectors in the group of processes was less than 0.25 percent during the initial or last required monitoring period. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor at least 50 percent of the connectors in the first 4 years and the remainder of the connectors within the next 4 years. If the percent leaking connectors in the first 4 years is equal to or greater than 0.35 percent, the monitoring program shall revert at that time to the appropriate monitoring frequency specified in paragraph (b)(4)(iii)(C), (D), or (E) of §63.1255. [40 CFR §63.1255(b)(4)(iii)(F)]
- iv. Section 63.178 shall apply except:
- a) For pumps, the phrase “at the frequencies specified in Table 1 of subpart” GGG in §63.178I(3)(iii) shall mean “quarterly” for the purposes of subpart GGG. [40 CFR §63.1255(b)(4)(iv)(B)]
- v. Section 63.180 shall apply except §63.180(b)(4)(ii)(A) through (C) shall not apply. Instead, calibration gases shall be a mixture of methane and air at a concentration of approximately, but no less than, 10,000 parts per million methane for agitators; 2,000 parts per million for pumps; and 500 parts per million for all other equipment, except as provided in §63.180(b)(4)(iii). [40 CFR §63.1255(b)(4)(v)]
- vi. When §§63.171, 63.172, 63.174, 63.178, and 63.180 reference other sections in subpart H of part 63, the references shall mean those sections specified in paragraphs (b)(2) and (b)(4)(i) through (v) of §63.1255, as applicable. [40 CFR §63.1255(b)(4)(vi)]
3. Standards for Pumps in Light Liquid Service and Agitators in Gas/Vapor Service and in Light Liquid Service.
- a. The provisions of §63.1255 apply to each pump that is in light organic HAP liquid service, and to each agitator in organic HAP gas/vapor service or in light organic HAP liquid service. [40 CFR §63.1255I(1)]

- b. *Monitoring.* Each pump and agitator subject to §63.1255 shall be monitored quarterly to detect leaks by the method specified in §63.180(b) except as provided in §§63.177, 63.178, paragraph (f) of §63.1255, and paragraphs (c)(5) through (9) of §63.1255. [40 CFR §63.1255(c)(2)(i)]
- c. *Leak definition.* According to 40 CFR §63.1255I(2)(ii), The instrument reading, as determined by the method as specified in §63.180(b), that defines a leak is:
 - i. For agitators, an instrument reading of 10,000 parts per million or greater. [40 CFR §63.1255I(2)(ii)(A)]
 - ii. For pumps, an instrument reading of 2,000 parts per million or greater. [40 CFR §63.1255I(2)(ii)(B)]
- d. *Visual Inspections.* According to 40 CFR §63.1255I(2)(iii), each pump and agitator shall be checked by visual inspection each calendar week for indications of liquids dripping from the pump or 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 procedure specified in either paragraph I(2)(iii)(A) or (B) of §63.1255 prior to the next weekly inspection.
 - i. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor the pump or agitator by the method specified in §63.180(b). If the instrument reading indicates a leak as specified in §63.1255(c)(2)(ii), a leak is detected. [40 CFR §63.1255(c)(2)(iii)(A)]
 - ii. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall eliminate the visual indications of liquids dripping. [40 CFR §63.1255I(2)(iii)(B)]
- e. *Repair provisions.*
 - i. When a leak is detected pursuant to paragraph I(2)(i), I(2)(iii)(A), (c)(5)(iv)(A), or (c)(5)(vi)(B) of §63.1255, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in paragraph (b)(4)(i) of §63.1255. [40 CFR §63.1255(c)(3)(i)]
 - ii. According to 40 CFR §63.1255I(3)(ii), the first attempt at repair shall be made no later than 5 calendar days after the leak is detected. First attempts at repair include, but are not limited to, the following practices where practicable:
 - a) Tightening of packing gland nuts.

- b) Ensuring that the flush seal is operating at design pressure and temperature.

f. *Calculation of percent leakers.*

- i. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall decide no later than the end of the first monitoring period what groups of processes will be developed. Once Pfizer Pharmaceuticals LLC (CRUCE DAVILA) has decided, all subsequent percent calculations shall be made on the same basis. [40 CFR §63.1255I(4)(i)]
- ii. If, calculated on a 1-year rolling average, the greater of either 10 percent or three of the pumps in a group of processes leaks, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor each pump once per month, until the calculated 1-year rolling average value drops below 10 percent or three pumps, as applicable. [40 CFR §63.1255I(4)(ii)]
- iii. The number of pumps in a group of processes shall be the sum of all the pumps in organic HAP service, except that pumps found leaking in a continuous process within 1 quarter after startup of the pump shall not count in the percent leaking pumps calculation for that one monitoring period only. [40 CFR §63.1255I(4)(iii)]
- iv. According to 40 CFR §63.1255I(4)(iv), the percent leaking pumps shall be determined by the following Equation:

$$\%P_L = [(P_L - P_S) / (P_I - P_S)] * 100$$

Where:

$\%P_L$ = percent leaking pumps.

P_L = number of pumps found leaking as determined through periodic monitoring as required in paragraphs I(2)(i) and (ii) of §63.1255.

P_I = total pumps in organic HAP service, including those meeting the criteria in paragraphs I(5) and (6) of §63.1255.

P_S = number of pumps in a continuous process leaking within 1 quarter of startup during the current monitoring period.

- g. *Exemptions.* According to 40 CFR §63.1255I(5), Each pump or agitator equipped with a dual mechanical seal system that includes a barrier fluid system is exempt from the requirements of paragraphs I(1) through I(4)(iii) of §63.1255, provided the following requirements are met: