

G. Monitoring Requirements

1. The owner or operator of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard as specified in §63.1258. During the initial compliance demonstration, maximum or minimum operating parameter levels, as appropriate, shall be established for emission sources that will indicate the source is in compliance. Test data, calculations, or information from the evaluation of the control equipment design shall be used to establish the operating parameter level. [40 CFR §63.1258(a)]
2. Except as specified in paragraph (b)(1)(i) of §63.1258, for each control equipment, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall install and operate sampling equipment and operate within the established parameter levels to ensure continued compliance with the standard. Sampling parameters are specified for control scenarios in Table 4 of subpart GGG and in paragraphs (b)(1)(ii) through (xi) of section 63.1258 of the 40 CFR.
 - a. For control equipment that control vent streams totaling less than 1 ton/yr HAP emissions, before control, sampling shall consist of a daily verification that the equipment is operating properly. If the control equipment is used to control batch process vents alone or in combination with other streams, the verification may be on a per batch basis. This verification shall include, but not be limited to, a daily or per batch demonstration that the unit is working as designed and may include the daily measurements of the parameters described in (b)(1)(ii) through (x) of §63.1258. [40 CFR §63.1258(b)(1)(i)]
3. *Procedures for setting parameter levels for control equipment used to control emissions.*
 - a. *Small control equipment.* Except as provided in paragraph (b)(1)(i) of this section, for equipment controlling less than 10 tons per year of HAP for which a performance test is not required, the parametric levels shall be set based on the design evaluation required in §63.1257(d)(3)(i). If a performance test is conducted, the sampling parameter level shall be established according to the procedures in (b)(3)(ii) of this section. [40 CFR §63.1258(b)(3)(i)]
 - b. *Large control equipment.* According to the requirements of 40 CFR section 63.1258(b)(3)(ii), for equipment controlling greater than 10 tons per year of HAP for which a performance test is required, the parameter level must be established as follows:
 - i. If the operating parameter level to be established is a maximum, it must be based on the average of the values from each of the three test runs. [40 CFR §63.1258(b)(3)(ii)(A)]

- ii. If the operating parameter level to be established is a minimum, it must be based on the average of the values from each of the three test runs. [40 CFR §63.1258(b)(3)(ii)(B)]
 - iii. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may establish the parametric sampling level(s) based on the performance test supplemented by engineering assessments and manufacturer's recommendations. Performance testing is not required to be conducted over the entire range of expected parameter values. The rationale for the specific level for each parameter, including any data and calculations used to develop the level(s) and a description of why the level indicates proper operation of the control equipment shall be provided in the Pre-compliance report. [40 CFR §63.1258(b)(3)(ii)(C)]
- c. *Parameters for control equipment controlling batch process vents.* For equipment controlling batch process vents alone or in combination with other streams, the parameter level(s) shall be established in accordance with one of the following paragraphs:
- i. If more than one batch emission episode has been selected to be controlled, a single level for the batch process(es) shall be determined from the initial compliance demonstration. [40 CFR §63.1258(b)(3)(iii)(A)]
 - ii. Instead of establishing a single level for the batch process(es), as described in paragraph (b)(3)(iii)(A) of §63.1258, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may establish separate levels for each batch emission episode, selected to be controlled. If separate monitoring levels are established, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must provide a record indicating at what point in the daily schedule or log of processes required to be recorded per the requirements of §63.1259(b)(9) the parameter being sampled changes levels and must record at least one reading of the new parameter level, even if the duration of sampling for the new parameter is less than 15 minutes. [40 CFR §63.1258(b)(3)(iii)(B)]
4. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may request approval to sample parameters other than those required by paragraphs (b)(1)(ii) through (ix) of §63.1258. The request shall be submitted according to the procedures specified in §63.8(f) or included in the Pre-compliance report. [40 CFR §63.1258(b)(4)]

5. *Sampling for the alternative standards*
 - a. For control equipment that is used to comply with the provisions of §63.1253(d) or §63.1254I, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall sample and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the equipment is functioning in achieving the HAP removal required by this subpart using the Continuous Emissions Sampling Systems (CEMS) as specified in paragraphs (b)(5)(i)(A) through (D) of §63.1258. [40 CFR §63.1258(b)(5)(i)]
6. The owner or operator of any affected source complying with the provisions of §63.1254(a)(2) shall demonstrate continuous compliance with the 900 and 1,800 kg/yr emission limits by calculating daily 365-day rolling summations of emissions. During periods of planned routine maintenance when emissions are controlled as specified in §63.1252(h), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must calculate controlled emissions assuming the HAP emissions are reduced by 93 percent. For any owner or operator opting to switch compliance strategy from the 93 percent control requirement to the annual mass emission limit method, as described in §63.1254(a)(1)(i), the rolling summations, beginning with the first day after the switch, must include emissions from the past 365 days. [40 CFR §63.1258(c)]
7. The owner or operator of any affected source complying with the requirements of §63.1255 of subpart GGG shall meet the sampling requirements described §63.1255 of subpart GGG. [40 CFR §63.1258(d)]
8. The owner or operator of any affected source that chooses to comply with the requirements of §§63.1252(e)(2) and (3) shall calculate a yearly rolling average of kg HAP consumption per kg production and kg VOC consumption per kg production every month or every 10 batches. Each rolling average kg/kg factor that exceeds the value established in §63.1257(f)(1)(ii) will be considered a violation of the emission limit. [40 CFR §63.1258(e)]
9. The owner or operator of any affected source that chooses to comply with the requirements of §63.1252(d) shall meet all sampling requirements specified in paragraphs (b)(1) and (3) of this section, as applicable, for all processes and storage tanks included in the emissions average. [40 CFR §63.1258(f)]
10. Leak inspection provisions for vapor suppression equipment.
 - a. Except as provided in paragraph (h)(9) §63.1258, for each vapor collection system, closed-vent system, fixed roof, cover, or enclosure required to comply with §63.1258, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the requirements of paragraphs (h)(2) through (8) of §63.1258. [40 CFR §63.1258(h)(1)]

- b. If a closed-vent system subject to §63.1258 is also subject to the equipment leak provisions of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the provisions of §63.1255 and is exempt from the requirements of §63.1258. [40 CFR §63.1258(h)(9)]
- c. Instead of complying with the provisions of paragraphs (h)(2) through (8) of §63.1258, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may 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 §63.1258(h)(10)]

H. Recordkeeping requirements

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the recordkeeping requirements in subpart A of part 63 as specified in Table 1 of subpart GGG and in paragraphs (a)(1) through (5) of §63.1259. [40 CFR §63.1259(a)]
2. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must keep the records mentioned in paragraphs (b)(1) to (13) of §63.1259 up-to-date and readily. [40 CFR §63.1259(b)]
3. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall keep records of each operating scenario, which demonstrates compliance with subpart GGG. [40 CFR §63.1259I]
4. The owner or operator of any affected source implementing the leak detection and repair (LDAR) program specified in §63.1255 of subpart GGG, shall implement the recordkeeping requirements in §63.1255 of §63.1255. [40 CFR §63.1259(d)]
5. The owner or operator of any facility that chooses to comply with the requirements of §63.1252(d) shall maintain up-to-date records of the information detailed in §63.1259(e)(1) through (4). [40 CFR §63.1259(e)]
6. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall keep records specified in paragraphs (i)(1) through (9) of §63.1259, as applicable [40 CFR §63.1259(i)].

I. Reporting requirements

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the reporting requirements detailed in the conditions below. Applicable reporting requirements of §§63.9 and 63.10 are summarized in Table 1 of subpart GGG. [40 CFR §63.1260(a)]

2. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall submit the applicable initial notification in accordance with §63.9(b) or (d). [40 CFR §63.1260(b)]
3. An owner or operator who is subject to §63.5(b)(3) shall submit to the Board and the EPA an application for approval of the construction of a new major affected source, the reconstruction of a major affected source, or the reconstruction of a major source such that the source becomes a major affected source subject to the standards. The application shall be prepared in accordance with §63.5(d). [40 CFR §63.1260(c)]
4. An owner or operator who is required by the Board or the EPA to conduct a compliance evaluation for a continuous monitoring system shall notify the Board and the EPA of the date of the compliance evaluation as specified in §63.8(e)(2). [40 CFR §63.1260(d)]
5. For new sources, the Pre-compliance report shall be submitted at least six months before the compliance date of the standard. For new sources, the Pre-compliance report shall be submitted to the Board and the EPA with the application for approval of construction or reconstruction. EQB and EPA have 90 days to approve or deny the plan. The plan shall be considered approved if the Board or EPA approves the plan in writing or if fails to approve the plan in writing. The 90-days period shall begin when EQB or EPA receive the application. If the request is denied, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must still be in compliance with the standard by the compliance date. To change any of the information submitted in the report, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall notify the Board and the EPA 90 days before the planned change is to be implemented. The Pre-compliance report shall include: [40 CFR §63.1260(e)]
 - a. Requests for approval to use alternative sampling parameters or requests to set sampling parameters according to §63.1258(b)(4). [40 CFR §63.1260(e)(1)]
 - b. Descriptions of the daily or per batch demonstrations to verify that the control equipment subject to §63.1258(b)(1)(i) is operating as designed. [40 CFR §63.1260(e)(2)]
 - c. A description of test conditions, and the corresponding sampling parameter values for parameters that are set according to §63.1258(b)(3)(ii)(C). [40 CFR §63.1260(e)(3)]
 - d. For owners and operators complying with the requirements of §63.1252(e), the P2 demonstration summary required in §63.1257(f). [40 CFR §63.1260(e)(4)]

- e. Data and rationale used to support an engineering assessment to calculate uncontrolled emissions from process vents as required in §63.1257(d)(2)(ii). [40 CFR §63.1260(e)(5)]
 - f. Data and other information supporting the determination of annual average concentrations by process simulation as required in §63.1257(e)(1)(ii). [40 CFR §63.1260(e)(6)]
 - g. Bench scale or pilot-scale test data and rationale used to determine annual average concentrations as required in §63.1257(e)(1)(ii)I. [40 CFR §63.1260(e)(7)]
6. The Notification of Compliance Status report required under §63.9 shall be submitted no later than 150 days after the compliance date and shall include:
- a. The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from the affected source. [40 CFR §63.1260(f)(1)]
 - b. The results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance. For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures. [40 CFR §63.1260(f)(2)]
 - c. Descriptions of sampling equipment, sampling frequencies, and the values of sampled parameters established during the initial compliance determinations, including data and calculations to support the levels established. [40 CFR §63.1260(f)(3)]
 - d. Listing of all operating scenarios. [40 CFR §63.1260(f)(4)]
 - e. Descriptions of worst-case operating and/or testing conditions for control equipment. [40 CFR §63.1260(f)(5)]
 - f. Identification of emission points subject to overlapping requirements described in §63.1250(h) and the authority under which the owner or operator will comply. [40 CFR §63.1260(f)(6)]
7. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall prepare Periodic reports in accordance with the following and submit them to the Board and the EPA:
- a. Except as provided in paragraphs (g)(1)(i), (ii), and (iii) of §63.1260, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall submit Periodic reports semiannually. The first report shall be submitted no later than 240 days after

the Notification of Compliance Status is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status is due. Each subsequent Periodic report shall cover the 6-month period following the preceding period. [40 CFR §63.1260(g)(1)]

- i. When the Board or the EPA determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source; or [40 CFR §63.1260(g)(1)(i)]
 - ii. Quarterly reports shall be submitted when the source experiences an exceedance of a temperature limit sampled according to the provisions of §63.1258(b)(1)(iii) or an exceedance of the outlet concentration sampled according to the provisions of §63.1258(b)(1)(x) or (b)(5). Once an affected source reports quarterly, the affected source shall follow a quarterly reporting format until a request to reduce reporting frequency is approved. If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) submits a request to reduce the frequency of reporting, the provisions in §63.10(e)(3)(ii) and (iii) shall apply, except that the phrase “excess emissions and continuous sampling system performance report and/or summary report” shall mean “Periodic report” for the purposes of §63.1260. [40 CFR §63.1260(g)(1)(ii)]
 - iii. When a new operating scenario has been operated since the last report, in which case quarterly reports shall be submitted. [40 CFR §63.1260(g)(1)(iii)]
- b. *Content of Periodic report.* Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall include the information that follows, as applicable.
- i. Each Periodic report must include the information in §63.10(e)(3)(vi)(A) through (I) and (K) through (M). For each continuous sampling system, the Periodic report must also include the information in §63.10(e)(3)(vi)(J). [40 CFR §63.1260(g)(2)(i)]
 - ii. If the total duration of excess emissions, parameter exceedances, or excursions for the reporting period is 1 percent or greater of the total operating time for the reporting period, or the total continuous sampling system downtime for the reporting period is 5 percent or greater of the total operating time for the reporting period, the Periodic report must include the following information:
 1. Sampling data, including 15-minute sampling values as well as daily average values of sampled parameters, for all operating days when the average values were outside the ranges

- established in the Notification of Compliance Status report or operating permit. [40 CFR §63.1260(g)(2)(ii)(A)]
2. Duration of excursions, as defined in §63.1258(b)(7). [40 CFR §63.1260(g)(2)(ii)(B)]
 3. Operating logs and operating scenarios for all operating scenarios for all operating days when the values are outside the levels established in the Notification of Compliance Status report or operating permit. [40 CFR §63.1260(g)(2)(ii)(I)]
 4. When a continuous sampling system is used, the information required in §63.10I(5) through (13). [40 CFR §63.1260(g)(2)(ii)(D)]
- iii. For each inspection conducted in accordance with §63.1258(h)(2) or (3) during which a leak is detected, the records specified in §63.1259(i)(7) must be included in the next Periodic report. [40 CFR §63.1260(g)(2)(iii)]
 - iv. For each vapor collection system or closed vent system with a bypass line subject to §63.1252(b)(1), records required under §63.1259(i)(6)(i) of all periods when the vent stream is diverted from the control equipment through a bypass line. For each vapor collection system or closed vent system with a bypass line subject to §63.1252(b)(2), records required under §63.1259(i)(6)(ii) of all periods in which the seal mechanism is broken, the bypass valve position has changed, or the key to unlock the bypass line valve was checked out. [40 CFR §63.1260(g)(2)(iv)]
 - v. The information in paragraphs (g)(2)(v)(A) through (D) of §63.1260 shall be stated in the Periodic report, when applicable.
 - a) No excess emissions. [40 CFR §63.1260(g)(2)(v)(A)]
 - b) No exceedances of a parameter. [40 CFR §63.1260(g)(2)(v)(B)]
 - vi. No excursions. [40 CFR §63.1260(g)(2)(v)(C)]
 - vii. No continuous sampling system has been inoperative, out of control, repaired, or adjusted. [40 CFR §63.1260(g)(2)(v)(D)]
 - viii. The information specified in paragraphs (g)(2)(vi)(A) through (C) of §63.1260 for periods of planned routine maintenance. [40 CFR

§63.1260(g)(2)(vi)] For each storage tank subject to the control requirements, periods of routine maintenance planned during which the control equipment does not comply with the specifications in section 63.1253(b) of the 40 CFR.

- ix. Each new operating scenario which has been operated since the time period covered by the last Periodic report. For each operating scenario, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall provide verification that the operating conditions for any associated control or treatment equipment have not been exceeded, and that any required calculations and engineering analyses have been performed. For the initial Periodic report, each operating scenario for each process operated since the due date of the Notification of Compliance Status Report shall be submitted. [40 CFR §63.1260(g)(2)(vii)]
- x. If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to comply with the provisions of §63.1253(b) or (c) by installing a floating roof, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall submit the information specified in §63.122(d) through (f) as applicable. References to §63.152 from §63.122 shall not apply for the purposes of subpart GGG. [40 CFR §63.1260(g)(2)(viii)]

8. Notification of process change [40 CFR §63.1260(h)]

- a. Whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, Pfizer Pharmaceuticals LLC (CRUCE DAVILA), shall submit the information specified in paragraphs (h)(1)(i) through (iv) of §63.1260 with the next Periodic report required under paragraph (g) of §63.1260. The report shall include:
 - i. A brief description of the process change. [40 CFR §63.1260(h)(1)(i)]
 - ii. A description of any modifications to standard procedures or quality assurance procedures. [40 CFR §63.1260(h)(1)(ii)]
 - iii. Revisions to any of the information reported in the original Notification of Compliance Status Report under paragraph (f) of §63.1260. [40 CFR §63.1260(h)(1)(iii)]
 - iv. Information required by the Notification of Compliance Status Report under paragraph (f) of §63.1260 for changes involving the addition of processes or equipment. [40 CFR §63.1260(h)(1)(iv)]

- b. All information as specified in paragraph (g) of section §63.1260 for each process or storage tank included in the emissions average;
 - c. Any changes of the processes or storage tanks included in the average.
 - d. The calculation of the overall percent reduction efficiency for the reporting period.
 - e. Changes to the Implementation Plan which affect the calculation methodology of uncontrolled or controlled emissions or the hazard or risk equivalency determination.
 - f. Every second semiannual or fourth quarterly report, as appropriate, shall include the results according to §63.1259(e)(4) to demonstrate the emissions averaging provisions of §§63.1252(d), 63.1257(g) and (h), 63.1258(f), and 63.1259(f) are satisfied. [40 CFR §63.1260(k)(1-6)]
12. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall notify the Administrator of the planned date of a performance test at least 60 days before the test in accordance with §63.7(b). Pfizer Pharmaceuticals LLC (CRUCE DAVILA) also must submit the test plan required by §63.7(c) and the emission profile required by 63.1257(b)(8)(ii) with the notification of the performance test. [40 CFR §63.1260(l)]
13. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may submit to the Administrator a request for an extension of compliance in accordance with §63.1250(f)(4). [40 CFR §63.1260(m)]

SECTION IX

- INSIGNIFICANT EMISSION UNITS

Note: The list of insignificant activities below was provided by the emission source in order to permit a better understanding of its operations. Given that it is not required to keep this list up-to-date, the activities may have suffered changes from the time when it was submitted.

Identification Emission Unit	Quantity	Description (Exemption Criteria)
Maintenance activities throughout the whole facility	4 times per year (approximately)	Activities at maintenance factory like brazing soldering equipment, welding, and soldering equipment used as an auxiliary media to the principal equipment of the source. (Appendix B(3)(ii)(E) of the RCAP)
Storage tanks with capacity of less than 10,000 gallons throughout the whole facility	7	Storage tanks with capacity of less than 10,000 gallons. (Appendix B(3)(ii)(N) of the RCAP)
Quality Control and Environmental Compliance Laboratories throughout the whole facility	2	Laboratories used solely for the purpose of quality control or environmental compliance testing that are associated with manufacturing, production or other industrial or commercial facilities. (Appendix B(3)(xxi) of the RCAP)
Manufacture of validation and test batches	---	Emissions of criteria pollutants is equal or less than 2 tons/year or 5 tons/year of a combination of the criteria pollutants and less than the de-minimis levels for hazardous pollutants in Appendix E. (Appendix B(2) of the RCAP)
Non routine tanks and equipments cleaning for employees entrance, preparation for maintenance or decomission throughout the whole facility	5 times per year (approximately)	Non routine tanks and equipments cleaning for employees entrance, preparation for maintenance or decomission (AppendixB(3)(xxvi) of the RCAP).
Training facilities to respond to fire, explosions and other that require and involve the use and combustion of fuels and chemicals.	1	Training facilities to respond to fire, explosions and other, required under the contingency and safety plan and that involve the use and combustion of fuels and chemicals as part of the training. (Appendix B(3)(xvi) of the RCAP)
Sampling conecctions and systems used exclusively to remove materials for analysis and tests, including air contaminants detectors and lines of escape.	(approximately) 20	Sampling conecctions and systems used exclusively to remove materials for analysis and tests, including air contaminants detectors and lines of escape. (Appendix B(3)(xxvii) of the RCAP)

Identification Emission Unit	Quantity	Description (Exemption Criteria)
Storage cabinets for solvents including packages.	20	Storage cabinets for solvents including packages. (Appendix B (3)(xxviii) of the RCAP)
Mobile and portable containers.	Approximately 40	Mobile and portable containers. (Appendix B(3)(xxxviii) of the RCAP)
Vents or stacks for drainage of deareators, transformers or MCC rooms.	5	Stacks or vent systems for buildings, transformation closed areas, control panels and electric engines and deareators. (Appendix B(3)(xxxix) of the RCAP)
Storage of substances in closed drums, barrels, bottles, or closed cylinders throughout the whole facility.	5	Storage of substances in closed drums, barrels, bottles or closed cylinders. (Appendix B(3)(xxxiv) of the RCAP)
Food preparation for cafeteria and dining hall services	2	Food preparation in cafeteria and dining hall services (Appendix (B)(3)(ii)(J) of the RCAP)
First aid or emergency medical care	1	First aid or emergency medical care including sterilization and preparation of medicine. (Appendix B(3)(ii)(F) of the RCAP)
Maintenance activities of the physical plant throughout the whole facility.	5 times per year (approximately)	Maintenance activities of the physical plant to take care of buildings and structures at the facility, including painting and roofing. (Appendix B(3)(ii)(H) of the RCAP.)
Activities of external maintenance of the land through all the installation including the maintenance of grass, painting buildings, etc.	-----	Activities of external maintenance of the land through all the installation including the maintenance of grass, painting buildings, etc. (Appendix B(3)(ii)(I) of the RCAP)
Engines of any vehicle, including but without limiting to, any motor vehicles, any forklift, tranctor, mobile construction equipment, including any auxiliary engine that provides cooling or refrigeration to the vehicle.	10	Engines of any vehicle, including but without limiting to, any motor vehicles, any forklift, tranctor, mobile construction equipment, including any auxiliary engine that provides cooling or refrigeration to the vehicle. (Appendix B(3)(iii) of the RCAP)
Application operations of sand blasting throughout the whole facility.	Once per year (approximately)	Operations of application of sand blasting in closed areas or outside, that satisfies the conditions with respect to particulate emission and fugitive emissions, location, reason of application, recordkeeping and reporting approval. (Appendix B(3)(viii) of

Identification Emission Unit	Quantity	Description (Exemption Criteria)
		the RCAP)
Pump seals	Approximately 75	Pump seals (Appendix B(3)(xxxxi) of the RCAP)
Rupture disks for systems managing gases.	Approximately 40	Rupture disks for systems managing gases (Appendix B (3)(xxxxii) of the RCAP)

SECTION X - PERMIT SHIELD

Pursuant to Rule 603(d) of the RCAP, compliance with the conditions of the permit shall be deemed compliance with any applicable requirements as of the date of permit issuance, provided that such applicable requirements are specifically identified in the permit. Likewise, it shall be deemed in compliance with any requirement specifically identified as Not Applicable in the permit. However, according to 40 CFR §63.6(e)(3)(ix), 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.

A. Non applicable requirements

Federal	Reason
National Emission Standards for Organic Liquids Distribution (40 CFR Part 63, Subpart EEEE)	Pfizer Cruce Dávila does not have any organic liquid with more than 5% by weight of listed in Table 1 of Subpart EEEE of Part 63 of the 40 CFR.
National Emission Standards for the Miscellaneous Manufacturing of Chemical Organics Substances (40 CFR Part 63, Subpart FFFF)	Pfizer Cruce Dávila does not produce any of the SOCOMI listed in Table 1 of the Subpart F, part 63 of the CFR.
40 CFR Part 82, Subpart B	It is not applicable because Pfizer Cruce Davila does not repair air conditioners from motor vehicles.

Attachments and Appendices

**ATTACHMENT 1- INFORMATION ABOUT THE EMISSION SOURCES
 LIST OF EMISSION UNITS OF CHEMICAL PLANT (EU-2)**

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
EU-Chemical Plant (EU-2) TRAIN # 1			
	K-82, REACTOR	QII-1	E-82-01, E-82-02 & S-303 or S-303 B
	K-82, REACTOR	QII-2	DC-X-311 (Non affected by Pharma MACT)
	K-84, REACTOR	QII-1	E-84-01, E-84-02 & S-303 or S-303 B
	K-84, REACTOR	QII-2	DC-X-311 (Non affected by Pharma MACT)
	C-411, CENTRIFUGE	QII-6	E-415-01
	S-2001, RECEIVER	QII-1	E-2001, E301 & S-303 or S-303 B
	C-412, CENTRIFUGE	QII-7	E-415-02
	S-2002, RECEIVER	QII-1	E-2002, E-301 & S-303 or S-303 B
	K-62, REACTOR	QII-1	E-62, E-301 & S-303 or S-303 B
	K-305, REACTOR	QII-1	E-305, E-301 & S-303 or S-303 B
	K-306, REACTOR	QII-1	E-306, E-301 & S-303 or S-303 B
	C-414, CENTRIFUGE	QII-8	E-415-03
	S-416, RECEIVER	QII-1	E-416, E-301 & S-303 or S-303 B
	ID-417, DRYING TOMBOLA	QII-2	DC-X-311 (Non affected by Pharma MACT)
	R-417-01, RECEIVER	QII-1	E-417-01 (Non affected by Pharma MACT)
	R-417-02, RECEIVER	QII-1	E-417-02 (Non affected by Pharma MACT)
	PIN MILL	QII-4	DC-X-310 (Non affected by Pharma MACT)

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
	R-1310, RECEIVER	QII-1	E-1310-01 (Non affected by Pharma MACT)
	R-1311, RECEIVER	QII-1	E-1311 (Non affected by Pharma MACT)
	WEIGHTING ROOM	QII-2	DC-X-311 (Non affected by Pharma MACT)
	R-499, TANK	Insignificant Activity	N/A
	ST-443, TANK	Insignificant Activity	N/A
	ST-444, TANK	Insignificant Activity	N/A
	M-337, VENTURI	QII-1	N/A
	M-2101, VENTURI	QII-1	N/A
	S-303, COLUMN	QII-1	N/A
	S-303, STACK	QII-1	N/A
EU-Chemical Plant (EU-2) TRAIN # 2			
	K-5146-01, TANK	QII-1	E-499 & S-303 or S-303 B
	K-5146-02, TANK	QII-1	E-499 & S-303 or S-303 B
	K-5146-03, TANK	QII-1	E-499 & S-303 or S-303 B
	K-112, REACTOR	QII-1	E-412-01, E-412-02 & S-303 or S-303 B
	K-112, REACTOR	QII-5 AND/OR QII-15	DC-X-312 and/or DC-X-401 (Non affected by Pharma MACT)
	K-104, REACTOR	QII-1	E-404-01, E-404-02 & S-303 o S-303 B
	K-104, REACTOR	QII-5 AND/OR QII-15	DC-X-312 and/or DC-X-401 (Non affected by Pharma MACT)
	R-111, RECEIVER	QII-1	E-491, E-499 & S-303 or S-303 B

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
	R-332, RECEIVER	Insignificant Activity	N/A
	K-113, REACTOR	QII-1	E-413-01, E-499 & S-303 or S-303 B
	ID-116, DRYNG TOMBOLA	QII-16	DC-X-402 (Non affected by Pharma MACT)
	K-301, REACTOR	QII-1	E-5149-01, E-499 & S-303 or S-303 B
	K-403, REACTOR	QII-1	E-5151-01, E-499 & S-303 or S-303 B
	C-5153-01, CENTRIFUGE	QII-12	E-5153-02
	C-5154-01, CENTRIFUGE	QII-13	E-5154-01
	K-5155-01, REACTOR	QII-1	E-5155-01, E-499 & S-303 or S-303 B
	K-5157-01, REACTOR	QII-1	E-5157-01, E-499 & S-303 or S-303 B
	K-5160-01, REACTOR	QII-1	E-5160-01, E-499 & S-303 or S-303 B
	K-5162-01, REACTOR	QII-1	E-5162-01, E-499 & S-303 or S-303 B
	C-402, CENTRIFUGE	QII-10	E-5164-01 (Non affected by Pharma MACT)
	C-5175-01, CENTRIFUGE	QII-11	E-5165-01
	ID-5177-01, DRYNG TOMBOLA	QII-2	DC-X-311 (Non affected by Pharma MACT)
	ID-126, DRYNG TOMBOLA	QII-2	DC-X-311 (Non affected by Pharma MACT)
	S-5178-01, RECEIVER	QII-1	E-5178-01, E-499 & S-303 or S-303 B
	S-5178-02, RECEIVER	QII-1	E-5178-02, E-499 & S-303 or S-303 B
	R-316, RECEIVER	QII-1	E-402, E-499 & S-303 or S-303 B
	S-1632, RECEIVER	QII-1	E-1632, E-499 & S-303 or S-303 B

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
	R-67 (S-6003), RECEIVER	QII-1	E-6007, E-6008 & S-303 or S-303 B
	S-2004, RECEIVER	QII-1	KC-127 A and/or KC-127 B & S-303 or S-303 B
	ST-0217-01, TANK	Insignificant Activity	N/A
	ST-0217-02, TANK	Insignificant Activity	N/A
	FS-400-01, COLUMN	QII-1	N/A
	FS-400-02, COLUMN	QII-1	N/A
	FS-400, STACK	QII-19	N/A
Train #1 & 2 (Common Use Equipments)			
	VP-0227-01, VACCUM PUMP	QII-20	E-0227-01 (Non affected by Pharma MACT)
	VP-0227-02, VACCUM PUMP	QII-20	E-0227-02 (Non affected by Pharma MACT)
	T-0227, TANK	QII-20	E-0227-01 or E-0227-02 (Non affected by Pharma MACT)
	T-0227-01, TANK	QII-20	E-0227-01 or E-0227-02 (Non affected by Pharma MACT)
	VP-0228-01, VACCUM PUMP	QII-21	E-0228-01 (Non affected by Pharma MACT)
	VP-0228-02, VACCUM PUMP	QII-21	E-0228-02 (Non affected by Pharma MACT)
	I-0228, TANK	QII-21	E-0228-01 or E-0228-02 (Non affected by Pharma MACT)
	T-0228-01, TANK	QII-21	E-0228-01 or E-0228-02 (Non affected by Pharma MACT)
	VP-0229-01, VACCUM PUMP	QII-22	E-0229-01 (Non affected by Pharma MACT)

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
	VP-0229-02, VACCUM PUMP	QII-22	E-0229-02 (Non affected by Pharma MACT)
	T-0229, TANK	QII-22	E-0229-01 or E-0229-02 (Non affected by Pharma MACT)
	T-0229-01, TANK	QII-22	E-0229-01 or E-0229-02 (Non affected by Pharma MACT)
	VP-301, VACCUM PUMP	QII-1	E-417-01, E-417-02 & S-303 (Non affected by Pharma MACT)
	VP-1630, VACCUM PUMP	QII-1	E-499 & S-303 (Non affected by Pharma MACT)
	VP-1631, VACCUM PUMP	QII-1	E-499 & S-303 (Non affected by Pharma MACT)
	VP-6007, VACCUM PUMP	QII-1	KC-127 A/B & S-303 (Non affected by Pharma MACT)
	VP-6008, VACCUM PUMP	QII-1	KC-127 A/B & S-303 (Non affected by Pharma MACT)
	VP-1310, VACCUM PUMP	QII-1	E-1310 & S-303 (Non affected by Pharma MACT)
	VP-1311, VACCUM PUMP	QII-1	E-1311 & S-303 (Non affected by Pharma MACT)
	VP-5178-01, VACCUM PUMP	QII-1	E-5178-01, E-5178-02 & S-303 (Non affected by Pharma MACT)
	Leaks Components (Pumps, Filters, Flanges, Valves, Conectors, PRD, Instrumentations, open end valves, open end lines, etc.)	QII-9 (Fugitives)	LDAR Programs of RCRA Subpart BB and LDAR of Pharma MACT