

- d. regarding electricity generators, it must list the hours recorded in the meter. This schedule will be used to calculate the cumulative fuel consumption
- e. will add all fuel amounts stated in item (c) during the year. This total shall not exceed the maximum fuel consumption limit allowed
- (vi) Records shall be maintained in the facility for evaluation and review by the technical staff of the Board when requested. The Board will use these records to verify when the portable units were operating, to identify where they were operating and to determine if the fuel consumption limit authorized in this permit was exceeded.
- (vii) The fuel consumption in each portable units shall be maintained on a daily basis in a rolling period of 365 days. The calculation of fuel consumption during any 365-day period shall be calculated by adding the fuel consumption of each day to the total fuel consumption of the previous 364 days.
- (viii) The permittee shall calculate the emissions allowed for portable combustion units using emission factors from AP-42 or Airs Facility Subsystem. The emission calculation shall be based on the cumulative fuel consumption of all units operated during the year.

Section VI - Emission Unit Requirements for Alternate Operating Scenarios

- A. For Alternate Operating Scenarios: McNeil is allowed to burn B20¹⁰ biodiesel mixture as an alternative fuel in the B-1, B-2, B-3, B-4 and B-5 units. [PFE-03-44-0704-0061-II-C]. For Alternate Scenarios, McNeil shall comply with the following:
 - (i) All applicable requirements (sampling, test methods and reporting) of the Normal Operating Scenario appearing in Section V of this permit.
 - (ii) The fuel to be burned corresponds with a fuel mixture (B20)¹¹ consisting of diesel (maximum S% of 0.5) and biodiesel (maximum S% of 0.0).
 - (iii) 1.2%¹² increase in NOx emissions for each unit in the alternate scenario is presumed, until new sampling data is obtained. If biodiesel is used in these units, sampling should be performed to determine the emissions of NOx using diesel and using biodiesel during the first 90 days of biodiesel used in the units.

1. Tests shall be conducted as provided in RCAP Rule 106.

¹⁰A blend of biodiesel fuel that meets ASTM D6751 specifications with diesel fuel; designated as B20, which represents 20 percent by volume of the biodiesel fuel in the mixture.

¹¹Fuel prepared by the manufacturer according to the specifications of ASTM D7467 – 10 and that complies with the EPA registration for Fuel Manufacturers.

¹²According to emission calculations included in the Title V Permit application.

2. If the results exceed the presumption of 1.2% increase, Mc Neil must request a modification to its construction permit PFE-03-44-0704-0061-II-C to reflect the increase in NOx.

Section VII - Recordkeeping Requirements

- A. McNeil shall prepare and update on a monthly basis the records of the hours of operation, fuel consumption and sulfur percent for ROTOR, INENGS, FIRE 1 and FIRE 2, FP-002, EG-2H and ICENG PE-1 units.
- B. McNeil shall prepare and update on a daily basis fuel consumption records and sulfur percent for the B-1, B-2, B-3, B-4, B-5, SB-1, SB4, SB5 and EG-03 units.
- C. The fuel consumption of any 12 consecutive months will be calculated through the sum of the total monthly consumption in each unit during the previous 11 months.
- D. McNeil shall have available at the facility at all times copies of the Emergency Plan required under Rule 107 of the RCAP.
- E. McNeil shall maintain records of fire control activities related to research or training.
- F. McNeil shall maintain records of purchases of refrigerant¹³ and refrigerant added to devices or equipment normally containing 50 or more pounds of refrigerant. [40 CFR §82.166]
- G. All monitoring records, fuel sampling test results, calibration test results, charts produced by instrumentation, all the reports and logs must be retained for a period of five years after the date they are recorded and shall be available at the request of the EPA or the Board. All rolling averages are calculated on daily basis.
- H. McNeil shall write down in a record, contemporaneously with the change from one operating scenario to another authorized under Section VI of this permit, the scenario under which it is operating. McNeil shall keep this record at the facility at all times.

Section VIII - Reporting Requirements

- A. Certification of Compliance: According to RCAP Rule 602(c)(2)(ix)(c), McNeil shall submit a compliance certification annually. The compliance certification shall be submitted to both the EQB and the EPA¹⁴ no later than April 1st of each year covering the previous calendar year. The compliance certification must include, but shall not be limited to, the information required in RCAP Rule 603(c).

¹³ As defined in 40 CRF 82.152

¹⁴ JCA certification should be directed to: Manager, Air Quality Area, PO Box 11488, San Juan, PR 00910. The EPA certification should be directed to: U.S. Environmental Protection Agency, 48 Carr. 165 Suite 7000, Guaynabo, P.R. 00968-8073.

- B. Emissions Calculations: No later than April 1st of each year, McNeil shall send the calculation of the actual emissions for the previous calendar year. The emissions calculation shall be provided in the forms prepared by the EQB for such purpose and the responsible official will certify that all information submitted is true, correct and representative of the of the permit activity. Emission calculations must include, but not be limited to, emissions PM/PM₁₀, NO_x, COV, CO, Pb, SO₂, HAP's and GHGs expressed as CO_{2e}.
- C. In Accordance with Rule 603(a)(5)(i) of the RCAP, McNeil shall submit biannual reports of the required sampling, on October 1st and April 1st of each year, respectively, or more frequently if required by the underlying applicable requirements or by the Board. All instances of deviations from permit requirements must be clearly identified in such reports. The responsible official must certify all required reports as established under Rule 602(c) (3) of the RCAP.
-  D. Monthly Fuel Consumption Reports: McNeil must submit a monthly report for units B-1, B-2, B-3, B-4, B-5, SB-001, SB-004, SB-005 and EG-03 on the sulfur content in percent by weight and daily fuel consumption in each unit. This report must be submitted to the Board to the attention of the Chief of the Data Validation and Mathematical Modeling Division during the first 30 days of the next month for which the report is representative.
- E. Fuel Consumption Annual Reports: The permittee shall submit annually a report on the sulfur content in weight percent and monthly fuel consumption for ROTOR, INENGS, FIRE 1 and FIRE 2, FP-002, EG-2H and ICENG PE-1 units. This report must be submitted to the Board to the attention of the Chief of the Data Validation and Mathematical Modeling Division during the first 15 days of next year for which the report is representative.
- F. McNeil shall submit to the Board copies of all reports required by 40 CFR Part 60, Subpart Dc sent to the EPA.
- G. In accordance with RCAP Rule 603 (a)(5)(ii), any deviation resulting from upset conditions (such as a sudden malfunction or unexpected rupture) or from emergency as defined under RCAP Rule 603(e) shall be reported within the next two (2) working days.
- H. In accordance with RCAP Rule 603(a)(5)(ii)(b), McNeil shall notify the Board within the next 24 hours of any deviation that results in the release of hazardous air pollutants that continues for more than an hour in excess of the applicable limit. In case of a release of any regulated air pollutant that continues for more than two hours in excess of the applicable limit, the Board will be notified within 24 hours of the deviation. McNeil shall also submit to the Board, within 7 days of the deviation, a detailed written report which includes probable causes, time and duration of the deviation, remedial action taken and the steps they are taking to prevent reoccurrence. [State-only enforceable condition]
- I. McNeil shall submit two copies to the Board of the written report of the results of all the emissions sampling within 60 days after completing the performance tests. [RCAP Rule 106(E)]

J. McNeil shall comply with the applicable notification requirements of 40 CFR Part 60 and Part 63, Subpart A by the dates specified.

Section IX - Insignificant Emission Units

McNeil provided the following list of insignificant activities for a better understanding of its operations and the distribution of its equipment. Since there is no requirement to update this list, activities may have changed since the time it was submitted, however McNeil shall include the list of insignificant activities that are exempted because of size or production rate and some may require a construction permit under Rule 203 of RCAP.

Emission Unit Identification	Description (Exemption basis)
Tablets and Caps Printing	RCAP Appendix B (3)(ii)(P)
31 ozone generating units	RCAP Appendix B (3)(ii)(P)
1 Methanol Storage Tank - MST-1 of 1,500 gallons	RCAP Appendix B (3)(ii)(N)
1 Acetone Storage Tank - AST-1 of 7,500 gallons	RCAP Appendix B (3)(ii)(N)
1 Acetone Storage Tank - NO -AST-2 of 1,000 gallons	RCAP Appendix B (3)(ii)(N)
Propane Gas Storage Tank of 12,000 gallons	RCAP Appendix B (3)(ii)(P)
Solvent Transfer Pipe	RCAP Appendix B (3)(ii)(P) (Emits less than 1 ton of VOC per year)
Sand blasting operations in closed areas or exteriors, that satisfy the conditions related to particulate and fugitive emissions, localization, application rate, recordkeeping, and registration approval.	RCAP Appendix B (3)(viii)
Laboratories used only for quality control or environmental compliance testing that are associated with manufacturing, production or other business or commercial facilities.	RCAP Appendix B (3)(xxi)
Non routine cleaning of tanks and equipment for purposes of worker entry or in preparation for maintenance or decommissioning (except equipment subject to 40 CFR Part 63 Subpart GGG).	RCAP Appendix B(3)(xxvi)
Steam vents and leaks from boilers and steam distribution systems.	RCAP Appendix B(3)(xxxv)
Sampling Points and systems used exclusively to withdraw materials for testing and analysis including air contaminant detectors and vent lines.	RCAP Appendix B(3)(xxvii)
Office Activities	RCAP Appendix B(3)(ii)(A)
Stationary Water Storage Tanks	RCAP Appendix B(3)(i)(A)
Water treatment equipment, including sewers and sewer manholes if the VOC concentration in the water is less than 3,500 parts per billion by weight	RCAP Appendix B(3)(ii)(L)

Emission Unit Identification	Description (Exemption basis)
Coating Pans (1-19 (DC-8-DC-26))	RCAP Appendix B(3)(ii)(P)
Granulation Area SB-715, P3E-001	RCAP Appendix B(3)(ii)(P)
Building 2, DC-DFT-2-4	RCAP Appendix B(3)(ii)(P)
Diesel Fuel Storage Tank with a capacity of 50,000 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(ii)(P)
Diesel Fuel Storage Tank with a capacity of 30,000 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(ii)(P)
4 Diesel Fuel Storage Tanks with a capacity of 15,000 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(ii)(P)
2 Diesel Fuel Storage Tanks with a capacity of 600 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
8 Diesel Fuel Storage Tanks with a capacity of 500 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Diesel Fuel Storage Tanks with a capacity of 560 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Fuel Diesel Storage Tank with a capacity of 285 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Fuel Diesel Storage Tank with a capacity of 214 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Diesel Fuel Storage Tank with a capacity of 2,500 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Fuel Diesel Storage Tank with a capacity of 600 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Diesel Fuel Storage Tank with a capacity of 6,000 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Diesel Fuel Storage Tank with a capacity of 10,000 gallons	RCAP Appendix B(2)
Fuel Diesel Storage Tank with a capacity of 300 gallons	RCAP Appendix B(3)(ii)(N) and B(3)(xi)
Fuel Diesel Storage Tank with a capacity of 200 gallons	RCAP Appendix B(3)(ii)(N) and B(3)(xi)
<i>Fuel Oil</i> Storage Tank with a capacity of 250,000 gallons	RCAP Appendix B(2)
<i>Fuel Oil</i> Storage Tank with a capacity of 2,000 gallons	RCAP Appendix B(2)
<i>Fuel Oil</i> Storage Tank with a capacity of 400 gallons	RCAP Appendix B(3)(ii)(N) and B(3)(xi)
Cooling Tower	RCAP Rule 206 and Appendix B(3)(xxxiii)
Lunch Room	RCAP Rule 206 and Appendix B(3)(ii)(J)
Cleaning Tray	RCAP Appendix B(3)(ii)(P)
Laundry Room	RCAP Appendix B(3)(ii)(G)
Storage Areas (Class I and Class II)	RCAP Appendix B(2)

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Emission Unit Identification	Description (Exemption basis)
Activities in maintenance workshops such as brazing, welding and soldering equipment used as an aid to primary source equipment.	RCAP Appendix B(3)(ii)(E)
Waste Oil Tank with capacity of 2,000 gallons	RCAP Appendix B(3)(ii)(N) and B(3)(xi)
Room Glatt #1, DC-36	RCAP Appendix B(3)(ii)(P)
Room 526, DC-34	RCAP Appendix B(3)(ii)(P)
Mixing Room, DC-32	RCAP Appendix B(3)(ii)(P)
Vacuum System 2901-VAC-001 (Rooms 311, 313, 344 and 360)	RCAP Appendix B(3)(ii)(P) 0.34 ton/yr based in the management \leq 3,000 kg/day of solid pharmaceutical product controlled by a dust collector with a minimum efficiency of 95%. [PFE-44-0900-1692-I-II-C]

Section X - Permit Shield

In accordance with RCAP Rule 603(D), compliance with permit conditions shall be deemed compliance with any requirement applicable as of the date of permit issuance, but only if such applicable requirement is included and specifically identified in the permit. Likewise, it shall be considered in compliance with any requirement specifically identified in the permit as "Not Applicable".

A. Reasons for Non-Applicability

Code for the Non-Applicability Determination	
Code	Reason
40 CFR Part 63, Subpart GGG	National Emissions Standard for Hazardous Air Pollutants for Pharmaceutical Production. Not applicable to minor sources of hazardous air pollutants (HAP).
40 CFR Part 61, Subpart V	National Emissions Standard for Equipment Leaks. The facility has no components in HAP service.
40 CFR Part 63, Subpart G	National Emission Standards for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater. The facility is not a manufacturing site for Synthetic Organic Chemicals.
40 CFR Part 63, Subpart H	National Emissions Standard for Organic Hazardous Air Pollutants for Equipment Leaks. Applies to pharmaceutical production processes that use carbon tetrachloride or methyl chloride over 300 hours per year. The facility does not use carbon tetrachloride or methyl chloride in their pharmaceutical production processes.
40 CFR Part 60, Subpart Kb	It does not apply to tanks greater than or equal to 151 m ³ capacity to store liquid with an actual maximum vapor pressure of less than 3.5 kPa or greater or equal capacity of 75 m ³ but less than 151 m ³ storing liquid with an actual maximum vapor pressure of less than 15 kPa.

Code for the Non-Applicability Determination	
Code	Reason
40 CFR Part 60 Subpart Dc	Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units Not applicable to steam generating units (boilers) that were built before June 9, 1989 and with a capacity of less than 10 MMBtu/hr. Not applicable to emission units identified as B-1, B-2, B-3 and SB-001, because they were built on 1984, 1984, 1986, 1977, respectively. Not applicable to units SB-004 and SB-005 because their capacity is less than 10 MMBtu/hr.
40 CFR Part 63 Subpart DDDDD	National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial and Institutional Boilers The facility is not a Major Source of HAP.
40 CFR Part 60 Subpart IIII	Standards of Performance for Stationary Compression Ignition Internal Combustion Engines Not applicable to internal combustion engines except ICENG PE-1, because they were manufactured on or before 2005.
40 CFR Part 63, Subpart JJJJ	Standards of Performance for Stationary Spark Ignition Internal Combustion Engines There are no spark ignition internal combustion engines authorized in the facility.
Rule 406 of RCAP	Particulate Matter Emission Limit for Fuel Burning Equipment It does not apply to internal combustion engines of electric generators and fire pumps because they do not meet the definition of Equipment for Fuel Burning Rule 102 of the RCAP.

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- B. The permit shield covers any alternative operating scenario provided it is defined and permitted under the conditions of this permit.

Section XI - Permit Approval

Pursuant to the powers granted to the Environmental Quality Board by the Environmental Public Policy Act, Public Law Number 416 of September 22 of 2004, as amended, and after verifying the administrative file and compliance with the Uniform Administrative Procedures Act, Public Law Number 170 of August 12, 1988, as amended, the US Clean Air Act, the Puerto Rico Environmental Public Policy Act, and the Regulations for the Control of Atmospheric Pollution of Puerto Rico, the Environmental Quality Board approves this permit subject to the terms and conditions stated therein.

In San Juan, Puerto Rico, September 9, 2016.

ENVIRONMENTAL QUALITY BOARD

María de los Ángeles Ortiz
Alternate Member

Rebeca Acosta Pérez
Vice President



Weldin F. Ortiz Franco
President

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APPENDIX

Appendix I - Definitions y Abbreviations

A. Definitions:

1. Biodiesel¹⁵- Fuel comprising monoalkyl esters of long chain fatty acids derived from vegetable oil or animal fat, designated B100, and attaining the ASTM 6751 requirements.
2. Law - Federal Clean Air Act, as amended, *42 U.S. 7401, et seq.*
3. Responsible Official - See the definition of Responsible Official as established under the Regulation for Air Pollution Control of the Environmental Quality Board (1995).
4. Regulation - Regulation for the Control of Atmospheric Pollution of the Environmental Quality Board.
5. Title V - Title V of the Federal Clean Act (*42 U.S.C. 7661*).

B. Abbreviations

EPA	Environmental Protection Agency
AP-42	Compilation of Air Pollutant Emission Factors
ASTM	American Society for Testing and Materials
Btu	British Thermal Unit
HAP	Hazardous Air Pollutants
CFR	Code of Federal Regulations
CO	Carbon Monoxide
VOC	Volatile Organic Compounds
HAP	Hazardous Air Pollutants
EQB/Board	Environmental Quality Board of Puerto Rico
Lbs	Pounds
MMBtu	Million Btu

¹⁵ As defined by the ASTM.

NAAQS	National Ambient Air Quality Standards
NO _x	Nitrogen oxides
NSPS	New Source Performance Standards
Pb	Lead
PM	Particulate matter
PM ₁₀	Particulate matter with a aerodynamic mass diameter equal to or less than (10) microns
PSD	Prevention of Significant Deterioration
RCAP	Regulation for Air Pollution Control of the Environmental Quality Board
RMP	Risk Management Plan
SIC	Standard Industrial Classification
SO _x	Sulfur Oxide
SO ₂	Sulfur dioxide
VHAP	Volatile Hazardous Air Pollutants

C. Notifications Address

Permit Compliance and Modifications Notifications

Puerto Rico Environmental Quality Board
Air Quality Area
Box 11488
San Juan, PR 00910

Appendix II- Description of Control Equipment

Emission Point	Id. Control Equipment	Controlled Pollutant	CONTROL EQUIPMENT				Estimate Basis ^b
			Type ^a	Manufacturer/ Model No.	Efficiency %		
					Design	Actual	
F-216	DC-1	PM-10	10 (b) cartridges	Farr/50LL	95	> 95	A
F-217	DC-2	PM-10	10 (b) cartridges	Farr/16D	95	> 95	A
F-218	DC-3	PM-10	10 (b) cartridges	Farr/50LL	95	> 95	A
F-70	DC-4	PM-10	10 (b) cartridges	Torit/AFT 4-16	95	> 95	A
F-145	DC-5	PM-10	10 (b) cartridges	Torit/3DF24	95	>95	E- Manufacturing specifications
F-134	DC-6	PM-10	10 (b) cartridges	Torit/TD-2300	95	> 95	A
F-144	DC-7	PM-10	10 (b) cartridges	Torit/2DF12- 002	95	> 95	A
F-133	DC-8	PM-10	10 (b) cartridges	Farr/20L	95	95	A, E
F-135	DC-9	PM-10	10 (b) cartridges	Farr/GS16SQ	95	95	A, E
F-136	DC-10	PM-10	10 (b) cartridges	Farr/GS12SQ	95	95	A, E
F-137	DC-11	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E
F-138	DC-12	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E
F-139	DC-13	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E
F-141	DC-14	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E
F-142	DC-15	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E

Emission Point	Id. Control Equipment	Controlled Pollutant	CONTROL EQUIPMENT				Estimate Basis ^b
			TYPE ^a	Manufacturer/ Model No.	Efficiency %		
F-143	DC-16	PM-10	10 (b) cartridges	Farr/20L	95	95	A, E
F-140	DC-17	PM-10	10 (b) cartridges	Farr/20L	95	95	A, E
F-163	DC-18	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-164	DC-19	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-165	DC-20	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-166	DC-21	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-167	DC-22	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-168	DC-23	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-169	DC-24	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-170	DC-25	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-171	DC-26	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-191	DC-27	PM-10	10 (b) cartridges	Torit/DFT2-16	95	> 95	A
F-161	DC-30	PM-10	10 (b) cartridges	Torit/DFT2-24	95	> 95	A
EF-236	DCP-31	PM-10	10 (b) cartridges	Torit/DFT 3-6	99	>95	A

Emission Point	Id. Control Equipment	Controlled Pollutant	CONTROL EQUIPMENT				Basis the Estimate ^b
			TYPE ^a	Manufacturer/ Model No.	Efficiency %		
TO-1	TO-1	PM-10, methanol, acetone	10	Thermal Oxidizer	>98	99.91	A
EF211	EF-211 Filters 30% and 95% eff	PM-10	10 (b) cartridges		95	> 95	E-Manufacturing specifications
PHARMFG 2	DC-33	PM-10	10(b) cartridges		95	> 95	A
PHARMFG	DC-35	PM-10	10(b) cartridges		95	> 95	A

Control Equipment Codes

- 10a Filter (*baghouse*)
- 10b Others: Cartridges

Emissions Estimate Method Codes

- A. Stack test
- B. Material Balance
- C. Emission factor
- D. Engineering estimate
- E-Mfg - Manufacturer's design specifications

Appendix III - Control Equipment Volumetric Flow Rate

Control Equipment	Volumetric Flow Rate (scfm)
DC-1	26,400
DC-2	5,000
DC-3	27,400
DC-4	5,000
DC-6	3,000
DC-7	4,000
DC-27	4,000
DC-30	6,000
¹⁶ GLATT No. 1	7,600
¹⁶ GLATT No. 2	7,600
¹⁶ GLATT No. 3	7,600
¹⁶ GLATT No. 4	7,600
¹⁶ GLATT No. 5	7,600
¹⁶ GLATT No. 6	7,600
DC-5	7,800
EF-211	13,080
Vacuum system	175
DC-8	5,500
DC-9	5,500
DC-10	5,500
DC-11	5,500
DC-12	5,500
DC-13	5,500
DC-14	5,500
DC-15	5,500
DC-16	5,500
DC-17	5,500
DC-18	5,500
DC-19	5,500
DC-20	5,500
DC-21	5,500
DC-22	5,500
DC-23	5,500
DC-24	5,500
DC-25	5,500
DC-26	5,500
DC-31	2,500
DC-33	8,000
DC-35	4,000

¹⁶The units have their own filter systems. Fugitive emissions.

