



46-00005

MERCK SHARP &amp; DOHME / WEST POINT



COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF ENVIRONMENTAL PROTECTION  
AIR QUALITY PROGRAM

**TITLE V/STATE OPERATING PERMIT**

Issue Date: August 16, 2012  
Revision Date: January 5, 2017  
Revision Type: Modification, Significant


Effective Date: January 5, 2017  
Expiration Date: [REDACTED]

In accordance with the provisions of the Air Pollution Control Act, the Act of January 8, 1960, P.L. 2119, as amended, and 25 Pa. Code Chapter 127, the Owner, [and Operator if noted] (hereinafter referred to as permittee) identified below is authorized by the Department of Environmental Protection (Department) to operate the air emission source(s) more fully described in this permit. This Facility is subject to all terms and conditions specified in this permit. Nothing in this permit relieves the permittee from its obligations to comply with all applicable Federal, State and Local laws and regulations.

The regulatory or statutory authority for each permit condition is set forth in brackets. All terms and conditions in this permit are federally enforceable applicable requirements unless otherwise designated as "State-Only" or "non-applicable" requirements.

**TITLE V Permit No: 46-00005**

Federal Tax Id - Plant Code: 22-1261880-1

Owner Information	
Name: MERCK SHARP & DOHME CORP Mailing Address: 770 SUMNEYTOWN PIKE WP20-205 WEST POINT, PA 19486-8000	
Plant Information	
Plant: MERCK SHARP & DOHME / WEST POINT Location: 46 Montgomery County 46953 Upper Gwynedd Township SIC Code: 2834 Manufacturing - Pharmaceutical Preparations	
Responsible Official	
Name: STEVEN MONGIARDO Title: EX. DIR - GLOBAL FAC MGMT Phone (215) 652-2791	
Permit Contact Person	
Name: AMY EARLEY Title: SR. SPECIALIST Phone: (215) 652-4247	
[Signature]  JAMES D. REBARCHAK, SOUTHEAST REGION AIR PROGRAM MANAGER	



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Pages 5-7 redacted entirely

Pages 10-23 redacted entirely

Pages 25-26 redacted entirely

Page 29 redacted entirely

Pages 31-36 redacted entirely

Pages 40-42 redacted entirely

Pages 46-113 redacted entirely

Page 116 redacted entirely

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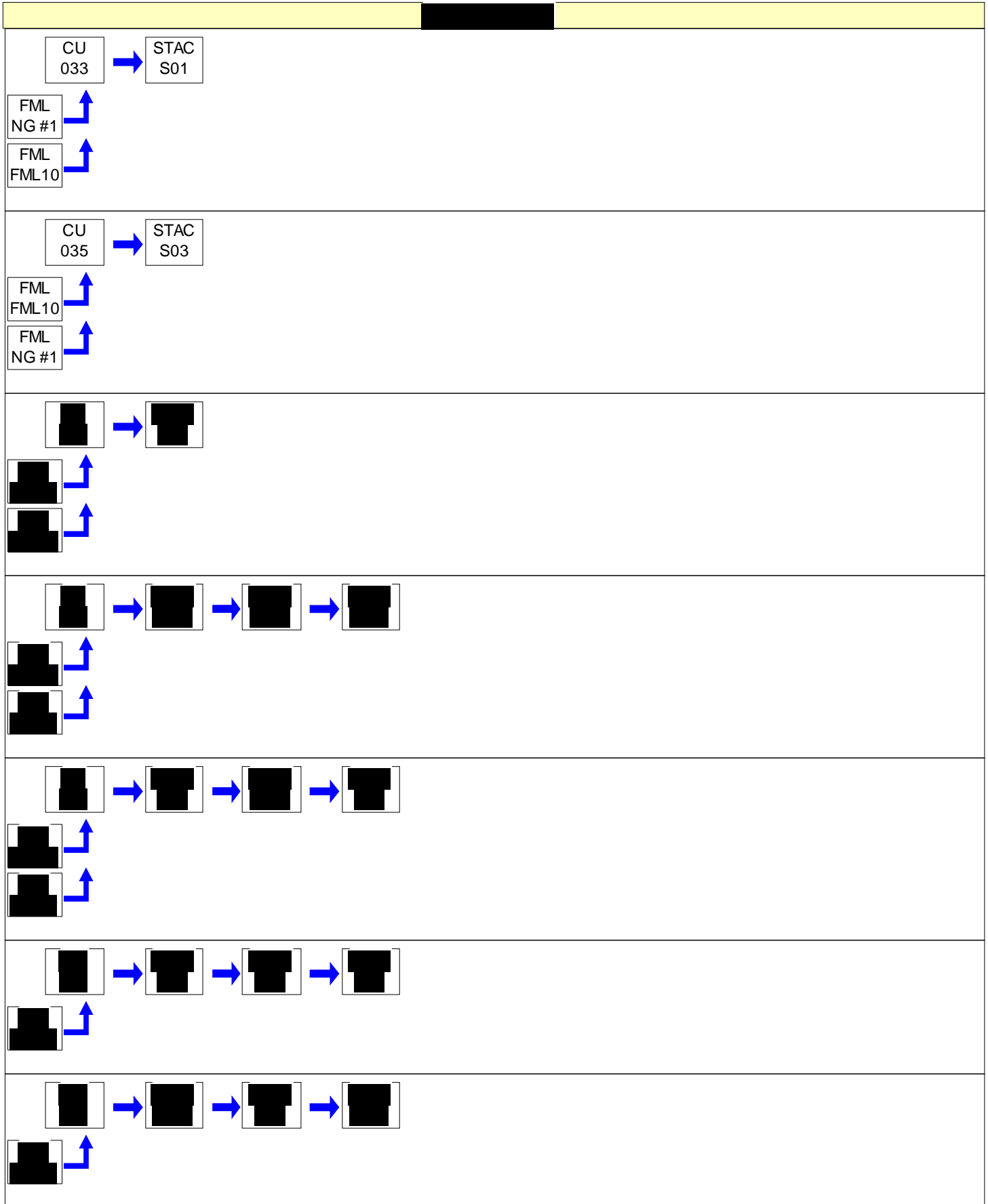
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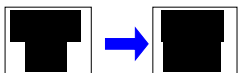
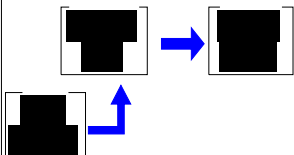
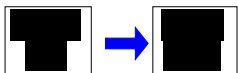
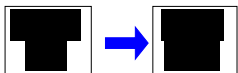
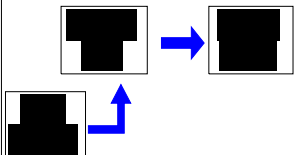
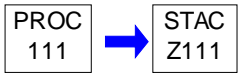
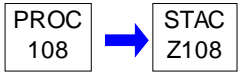
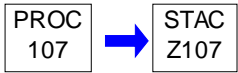
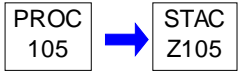
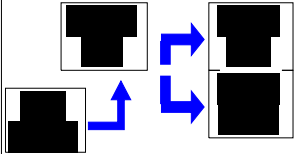
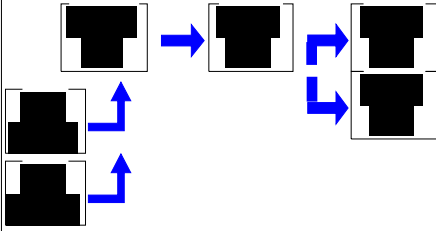


## SECTION A. Site Inventory List

[illegible]



# PERMIT MAPS



**SECTION C. Site Level Requirements**

[REDACTED]

[REDACTED]

# 009 [REDACTED]

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(c).]

VOC emissions from Research and Development activities shall not exceed eighteen (18) tons in any 12 consecutive month period. The permittee shall notify the Department in writing, before installing any new laboratories or pilot equipment. The permittee shall keep a record of the emissions of VOCs due to Research and Development activities at the West Point facility.

As of August 1, 2012, the following buildings comprise Research and Development activities toward the 18 ton VOC limit above: 1, 14, 16, 17, 20, 26, 28, 38, 42, 44, 45, 46, 75, 77, 78, 81, 82.

**II. TESTING REQUIREMENTS.**

[REDACTED]

**SECTION C. Site Level Requirements**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

# 018 [REDACTED]

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.100(e).]

The permittee shall maintain records of solvent purchases as a means of estimating VOC [REDACTED] emissions. [REDACTED]

**SECTION C. Site Level Requirements**

[REDACTED] to assure compliance with the R&D VOC emission limit found in Site Condition #008 (referring to VOC emissions from R&D activities).

These records shall be aggregated monthly and used in the 12 consecutive month VOC calculations.

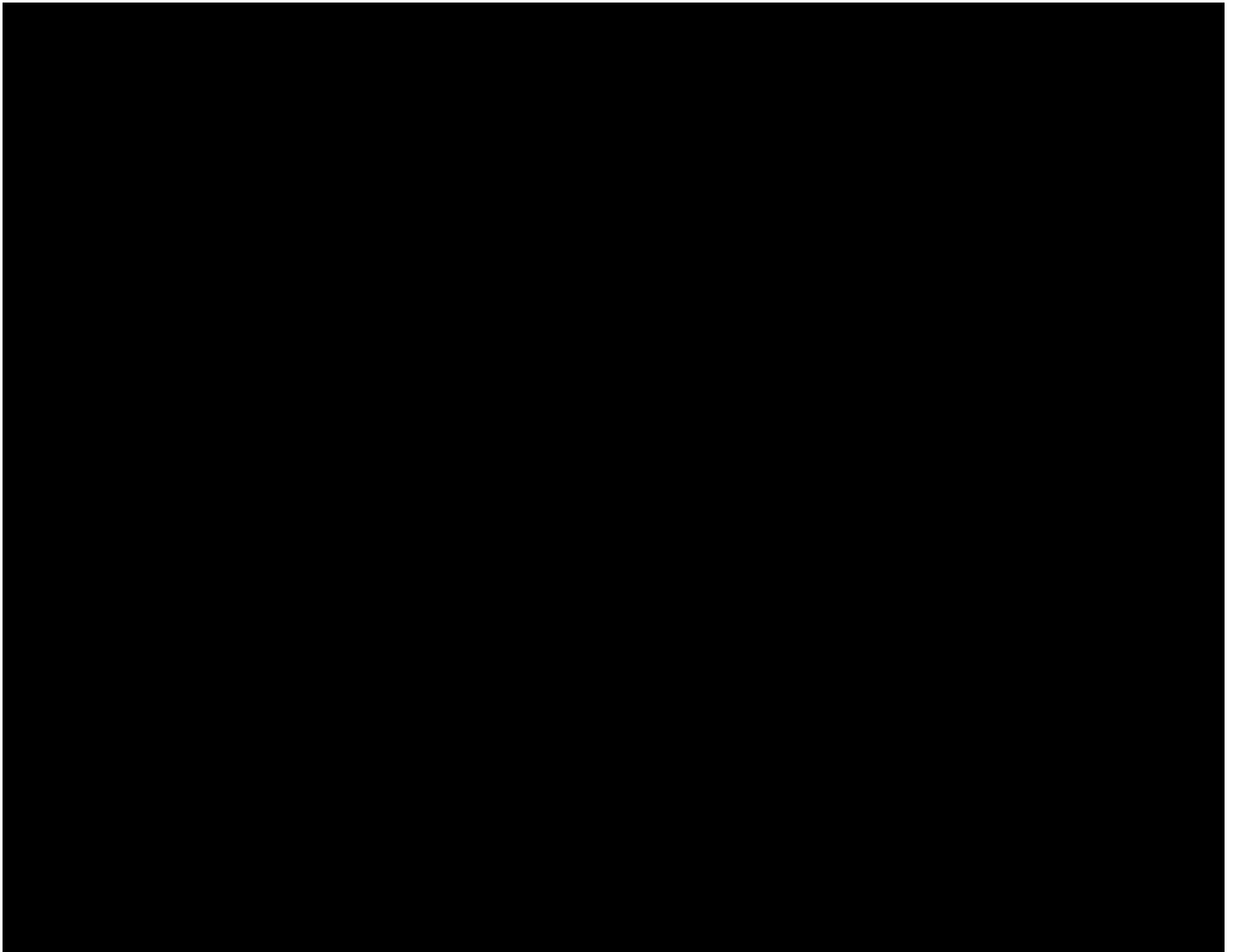
[REDACTED]

[REDACTED]

**V. REPORTING REQUIREMENTS.**

[REDACTED]



**SECTION C. Site Level Requirements**

# 034

[Additional authority for this permit condition is also derived from 25 Pa. Code §§ 129.91 and 129.100.]

Research & Development (R&D) sources shall be operated and maintained in accordance with good air pollution control practices.

The permittee shall provide annual training in responsible environmental laboratory practices to promote VOC emission reduction and to demonstrate compliance with the VOC emission limits.

# 035

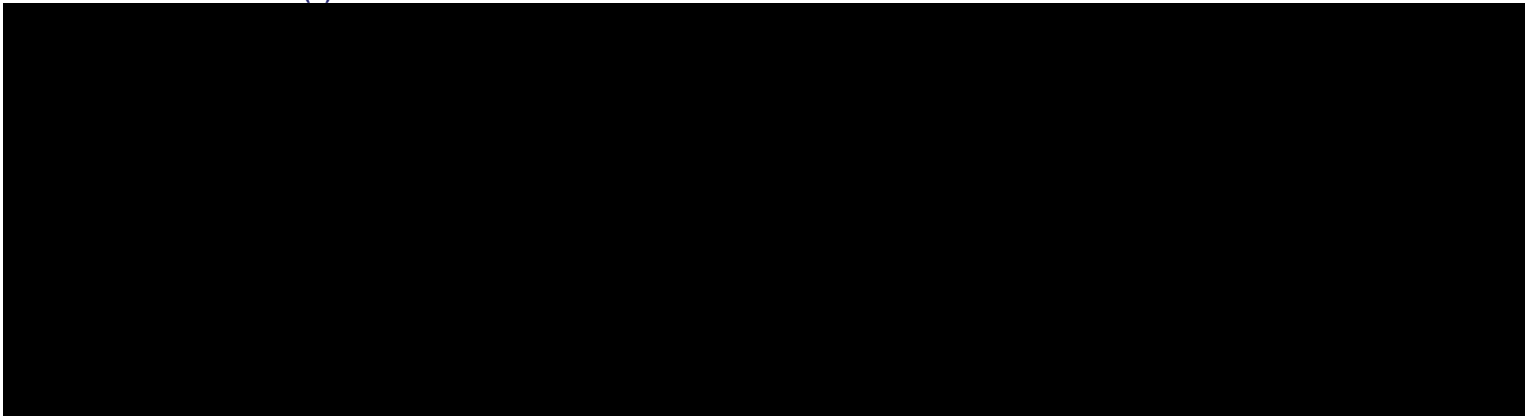
[Additional authority for this permit condition is also derived from 25 Pa. Code §§ 129.91 and 129.100.]

For use in demonstrating compliance with the VOC emission limits, the R&D VOC emissions shall be expressed as a quantity of solvents purchased, multiplied by a site-specific emission factor.

**SECTION D. Source Level Requirements**

Source ID: 033

Source Name: ERIE CITY BOILER 3

**I. RESTRICTIONS.****Emission Restriction(s).**

# 003

[Additional authority for this permit condition is also derived from 25 Pa. Code §§ 129.97(i) and 129.99.]

NOx emissions from this boiler, shall not exceed any of the following:

- (a) 0.15 lbs/MMBtu, on a daily basis when firing on natural gas;
- (b) 0.15 lbs/MMBtu, on a daily basis when firing on #2 fuel oil;

**SECTION D. Source Level Requirements****II. TESTING REQUIREMENTS.**

# 007

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.100(a)(4).]

The permittee shall conduct a Department-approved emissions source test for NO<sub>x</sub> emissions one time in each 5-year calendar period.

For the purpose of this condition, a 5-year calendar period is defined as beginning with the calendar year the latest stack test is performed and ending on December 31, five years later.

**III. MONITORING REQUIREMENTS.**

# 008

[additional authroity for this permit condition is also derived from 25 Pa. Code § 129.100(d).]

The permittee shall monitor the fuel type and hours of operation daily for use in demonstrating compliance with the NO<sub>x</sub> emission limits.

**IV. RECORDKEEPING REQUIREMENTS.**

# 009

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.100(d).]

The permittee shall record the fuel type and hours of operation daily for use in demonstrating compliance with the NO<sub>x</sub> limits for this boiler.

**SECTION D. Source Level Requirements**

Emission calculations and records shall be maintained as follows:

(a) NO<sub>x</sub> - monthly and on a 12-consecutive month basis; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

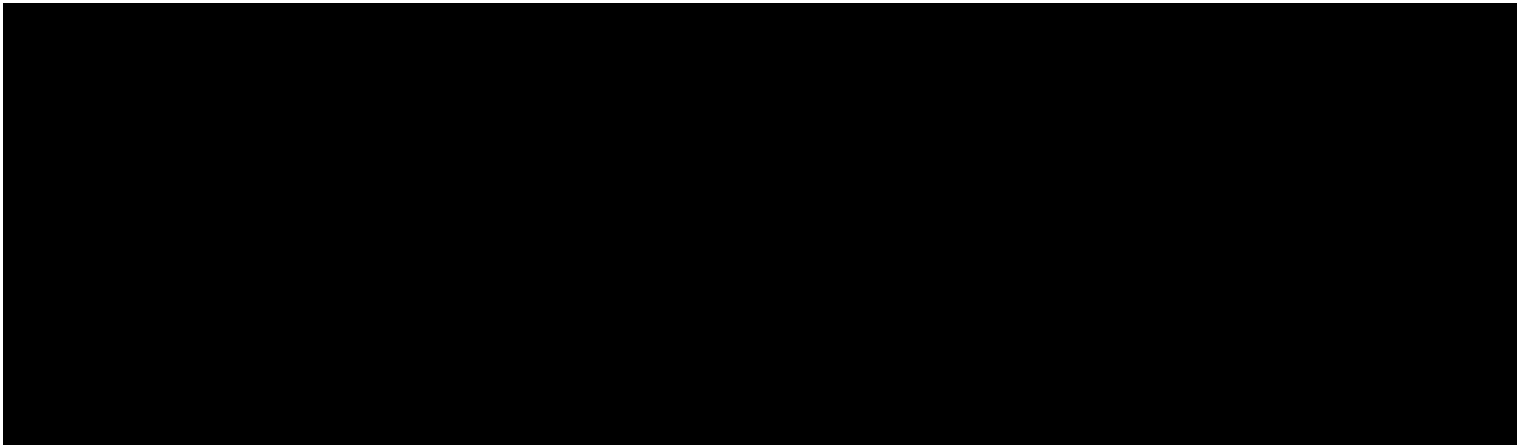
**SECTION D. Source Level Requirements**

Source ID: 035

Source Name: KEELER BOILER 5

**I. RESTRICTIONS.**

Emission Restriction(s).



# 003

[Additional authority for this permit condition is also derived from 25 Pa. Code §§ 129.91 and 129.99.]

NOx emissions from this boiler, shall not exceed any of the following:

(a) 0.20 lbs/MMBtu, on a daily basis when firing on natural gas;

(b) 0.20 lbs/MMBtu, on a daily basis when firing on #2 fuel oil;

**SECTION D. Source Level Requirements****II. TESTING REQUIREMENTS.**

# 007

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.100(a)(4).]

The permittee shall conduct a Department-approved emissions source test for NO<sub>x</sub> emissions one time in each 5-year calendar period.

For the purpose of this condition, a 5-year calendar period is defined as beginning with the calendar year the latest stack test is performed and ending on December 31, five years later.

**III. MONITORING REQUIREMENTS.**

# 008

[additional authroity for this permit condition is also derived from 25 Pa. Code § 129.100(d).]

The permittee shall monitor the fuel type and hours of operation daily for use in demonstrating compliance with the NO<sub>x</sub> emission limits for this boiler.

**IV. RECORDKEEPING REQUIREMENTS.**

# 009

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.100(d).]

The permittee shall record the fuel type and hours of operation daily for use in demonstrating compliance with the NO<sub>x</sub> emission limits for this boiler.

Emission calculations and records shall be maintained as follows:

**SECTION D. Source Level Requirements**

(a) NO<sub>x</sub> - monthly (lb/MMBtu) and on a 12 consecutive month basis; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

## SECTION D. Source Level Requirements

Source ID: 105

Source Name: BIOLOGICAL MANUFACTURING



### I. RESTRICTIONS.

#### Emission Restriction(s).

# 002

[additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(c).]

VOC area emissions from the disinfecting operations shall not exceed 34.22 tons in any 12 consecutive month period.

The disinfecting operations subject to this VOC limit are located in the following buildings: 28, 29, 38, 60, 65, and 76.

### III. MONITORING REQUIREMENTS.

# 004

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.100(d).]

The permittee shall monitor solvent purchases (or mass balance) for disinfecting operations, and shell freezer usage for shell freezer operations, on a monthly basis to assure compliance with the VOC emission limits for the point and area sources.

### IV. RECORDKEEPING REQUIREMENTS.

# 005

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(d).]

The permittee shall maintain monthly and 12-consecutive month records of the following:



**SECTION D. Source Level Requirements**

(b) disinfection operations.

- (1) VOC emission factors (based on the VOC content and density of disinfectant used, as provided by the supplier); and
- (2) total amount of each type of disinfectant.

**VI. WORK PRACTICE REQUIREMENTS.**

# 007

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(d).]

At a minimum, the following work practices shall be followed:

- (a) good housekeeping procedures for the storage, use, and disposal of solvents;
- (b) employee training detailing good work practices to control solvent usage for minimizing emissions;
- (c) periodic inspection of production and cleaning activities; and
- (d) solvent containers shall be closed when not in use.

# 008

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(d).]

Monthly solvent purchase records (or mass balance) and source-specific emission factors shall be used to calculate the VOC emissions from the disinfecting operations and demonstrate compliance with the area VOC emission limit for this source.

**SECTION D. Source Level Requirements**

Source ID: 107

Source Name: BUILDING 12

**I. RESTRICTIONS.****Emission Restriction(s).**

# 001

[Additional authority for (a) abd (b), below, is also derived from 25 Pa. Code § 129.99(c).]

Emissions shall not exceed the following in any 12 consecutive month period:

(b) VOC from the disinfecting operations - 30.6 tons;

**III. MONITORING REQUIREMENTS.**

# 003

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.100(d).]

The permittee shall monitor solvent purchases (or mass balance) for disinfecting operations on a monthly basis for use in calculating compliance with the VOC emission limits for the area and point sources.

**IV. RECORDKEEPING REQUIREMENTS.**

# 005

[Additional authority for (b), below is also derived from 25 Pa. Code § 129.100(d).]

The permittee shall maintain monthly and 12 consecutive month records of the following:

**SECTION D. Source Level Requirements**

[REDACTED]

(b) disinfection operations.

- (1) VOC emission factors (based on the VOC content and density of disinfectant used, as provided by the supplier); and
- (2) total amount of each type of disinfectant used.

**VI. WORK PRACTICE REQUIREMENTS.**

# 007 [REDACTED]

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(d).]

Monthly solvent purchase records (or mass balance) and source-specific emission factors shall be used to calculate the VOC emissions from the disinfecting operations [REDACTED]

# 008 [REDACTED]

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(d).]

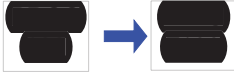
At a minimum, the following work practices shall be followed:

- (a) good housekeeping procedures for the use (dispensing only the amount needed), and disposal of solvents and solvent laden wipes into closed, non-absorbent, and non-leaking containers;
- (b) employee training detailing good work practices to control solvent usage for minimizing emissions;
- (c) periodic inspection of production and cleaning activities;
- (d) ordering cleaners and disinfectants only from company approved vendors; and
- (e) containers with solvent shall be closed or covered when not in use.

## SECTION D. Source Level Requirements

Source ID: 108

Source Name: BUILDING 66



### I. RESTRICTIONS.

#### Emission Restriction(s).

# 001

#### Operating permit terms and conditions

[Additional authority for (b), below, is also derived from 25 Pa. Code § 129.99(c).]

Emissions shall not exceed the following in any 12 consecutive month period:



(b) VOC from the disinfecting operations - 11.9 tons; and



### III. MONITORING REQUIREMENTS.

# 005

[Additional authority for this permit condition pertaining to VOC emissions is also derived from 25 Pa. Code § 129.100(d).]

The permittee shall monitor solvent purchases (or mass balance) for disinfecting operations on a monthly basis for use in calculating compliance with the VOC emission limits for the area sources.

**SECTION D. Source Level Requirements****IV. RECORDKEEPING REQUIREMENTS.**# 006 [REDACTED]  
[REDACTED]

[Additional authority for (b),below, is also derived from 25 Pa. Code § 129.100.]

The permittee shall maintain monthly and 12 consecutive month records of the following:

[REDACTED]  
(b) disinfection operations.

- (1) VOC emission factors (based on the VOC content and density of disinfectant used, as provided by the supplier); and
- (2) total amount of each type of disinfectant used.

**VI. WORK PRACTICE REQUIREMENTS.**# 008 [REDACTED]  
[REDACTED]

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(d).]

At a minimum, the following work practices shall be followed:

- (a) good housekeeping procedures for the use (dispensing only the amount needed), and disposal of solvents and solvent laden wipes into closed, non-absorbent, and non-leaking containers;
- (b) employee training detailing good work practices to control solvent usage for minimizing emissions;
- (c) periodic inspection of production and cleaning activities;
- (d) ordering cleaners and disinfectants only from company approved vendors; and
- (e) containers with solvent shall be closed or covered when not in use.

# 009 [REDACTED]  
[REDACTED]

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(d).]

Monthly solvent purchase records (or mass balance) and source-specific emission factors shall be used to calculate the VOC emissions from the disinfecting operations and demonstrate compliance with the area VOC emission limit for this source.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

## SECTION D. Source Level Requirements

Source ID: 111

Source Name: BUILDING 62



### I. RESTRICTIONS.

#### Emission Restriction(s).

# 001

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(c).]

VOC emissions from disinfection operations shall not exceed 7.08 tons in any 12 consecutive month period.

### III. MONITORING REQUIREMENTS.

# 002

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.100(c).]

The permittee shall monitor solvent purchases (or mass balances) for disinfecting operations on a monthly basis for use in calculating compliance with the VOC emission limit for this source.

### IV. RECORDKEEPING REQUIREMENTS.

# 003

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.100(d).]

The permittee shall maintain the following monthly and 12 consecutive month records of the disinfection operations:

- (a) VOC emission factors (based on the VOC content and density of disinfectant used, as provided by the supplier);
- (b) total amount of each type of disinfectant used; and
- (c) monthly and 12-consecutive month VOC emissions.

### VI. WORK PRACTICE REQUIREMENTS.

# 004

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(c).]

Monthly solvent purchase records (or mass balance) and source-specific emission factors shall be used to calculate the VOC emissions from the disinfecting operations and to demonstrate compliance with the area VOC emission limit for this source.

**SECTION D. Source Level Requirements**# 005 [REDACTED]  
[REDACTED]

[Additional authority for this permit condition is also derived from 25 Pa. Code § 129.99(c).]

At a minimum, the following work practices shall be followed:

- (a) good housekeeping procedures for the use (dispensing only the amount needed), and disposal of solvents and solvent laden wipes into closed, non-absorbent, and non-leaking containers;
  - (b) employee training detailing good work practices to control solvent usage for minimizing emissions;
  - (c) periodic inspection of production and cleaning activities;
  - (d) ordering cleaners and disinfectants only from company approved vendors; and
  - (e) containers with solvent shall be closed or covered when not in use.
-