

**Iowa Department of Natural Resources
Title V Operating Permit**

Name of Permitted Facility: Cambrex Charles City, Inc.

Facility Location: 1205 11th St., Charles City, IA 50616

Air Quality Operating Permit Number: 15-TV-007R1-M001

Expiration Date: May 17, 2025

Permit Renewal Application Deadline: November 17, 2024

EIQ Number: 92-4536

Facility File Number: 34-01-015

Responsible Official

Name: Joe Nettleton

Title: Vice President – Operations and Site Director

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This permit is issued in accordance with 567 Iowa Administrative Code Chapter 22, and is issued subject to the terms and conditions contained in this permit.

For the Director of the Department of Natural Resources



2/23/2023

Marnie Stein, Supervisor of Air Operating Permits Section

Date

Table of Contents

I. Facility Description and Equipment List	4
II. Plant - Wide Conditions.....	5
III. Emission Point Specific Conditions	16
IV. General Conditions.....	71
G1. Duty to Comply	
G2. Permit Expiration	
G3. Certification Requirement for Title V Related Documents	
G4. Annual Compliance Certification	
G5. Semi-Annual Monitoring Report	
G6. Annual Fee	
G7. Inspection of Premises, Records, Equipment, Methods and Discharges	
G8. Duty to Provide Information	
G9. General Maintenance and Repair Duties	
G10. Recordkeeping Requirements for Compliance Monitoring	
G11. Evidence used in establishing that a violation has or is occurring.	
G12. Prevention of Accidental Release: Risk Management Plan Notification and Compliance Certification	
G13. Hazardous Release	
G14. Excess Emissions and Excess Emissions Reporting Requirements	
G15. Permit Deviation Reporting Requirements	
G16. Notification Requirements for Sources That Become Subject to NSPS and NESHAP Regulations	
G17. Requirements for Making Changes to Emission Sources That Do Not Require Title V Permit Modification	
G18. Duty to Modify a Title V Permit	
G19. Duty to Obtain Construction Permits	
G20. Asbestos	
G21. Open Burning	
G22. Acid Rain (Title IV) Emissions Allowances	
G23. Stratospheric Ozone and Climate Protection (Title VI) Requirements	
G24. Permit Reopenings	
G25. Permit Shield	
G26. Severability	
G27. Property Rights	
G28. Transferability	
G29. Disclaimer	
G30. Notification and Reporting Requirements for Stack Tests or Monitor Certification	
G31. Prevention of Air Pollution Emergency Episodes	
G32. Contacts List	
V. Appendix A: Equipment Lists for EP 303 and 309	86
VI Appendix B: Links to Standards	89

Abbreviations

acfm.....	actual cubic feet per minute
CFR.....	Code of Federal Regulation
CE	control equipment
CEM.....	continuous emission monitor
°F.....	degrees Fahrenheit
EIQ.....	emissions inventory questionnaire
EP	emission point
EU	emission unit
gr./dscf	grains per dry standard cubic foot
IAC.....	Iowa Administrative Code
DNR	Iowa Department of Natural Resources
MVAC.....	motor vehicle air conditioner
NAICS.....	North American Industry Classification System
NSPS	new source performance standard
ppmv	parts per million by volume
lb./hr	pounds per hour
lb./MMBtu	pounds per million British thermal units
SCC.....	Source Classification Codes
scfm.....	standard cubic feet per minute
SIC	Standard Industrial Classification
TPY	tons per year
USEPA.....	United States Environmental Protection Agency

Pollutants

PM.....	particulate matter
PM ₁₀	particulate matter ten microns or less in diameter
SO ₂	sulfur dioxide
NO _x	nitrogen oxides
VOC	volatile organic compound
CO	carbon monoxide
HAP.....	hazardous air pollutant

I. Facility Description and Equipment List

Facility Name: Cambrex Charles City, Inc.

Permit Number: 15-TV-007R1-M001

Facility Description: Medicinal Chemicals & Botanicals Production (SIC 2833)

Equipment List⁽¹⁾

⁽¹⁾ Pursuant to 567 IAC 22.101(1)"c" any source that is required to obtain a Title V operating permit solely because of a NESHAP requirement, and which is not a major source, is required to obtain a Title V permit only for the emission unit(s) and related equipment causing the source to be subject to the Title V program. There are other emission units at this facility that are not included in the Title V operating permit.

Emission Point Number	Emission Unit Number	Emission Unit Description	DNR Construction Permit Number
EP 303	See Appendix A	Pharma I Production	95-A-445-S22
EP 304	R-3142	Reactor (Bypass)	12-A-561-S1
	R-3144	Reactor (Bypass)	
EP 306	R-3150	Reactor Tanks (Bypass)	13-A-176-S2
EP 308	R-3160	Hydrogen Bypass Vent	14-A-626-S2
	R-3186	Hydrogen Bypass Vent	
EP 309	See Appendix A	Pharma 1 Production - Flame Arrestor	19-A-067

II. Plant-Wide Conditions

Facility Name: Cambrex Charles City, Inc.
Permit Number: 15-TV-007R1-M001

Permit Conditions are established in accord with 567 Iowa Administrative Code rule 22.108

Permit Duration

The term of this permit is: Five (5) years from permit issuance
Commencing on: May 18, 2020
Ending on: May 17, 2025

Amendments, modifications and reopenings of the permit shall be obtained in accordance with 567 Iowa Administrative Code rules 22.110 - 22.114. Permits may be suspended, terminated, or revoked as specified in 567 Iowa Administrative Code Rules 22.115.

Emission Limits

Unless specified otherwise in the Source Specific Conditions, the following limitations and supporting regulations apply to all emission points at this plant required to be included in this Title V permit:

Opacity (visible emissions): 40% opacity
Authority for Requirement: 567 IAC 23.3(2)"d"

Sulfur Dioxide (SO₂): 500 parts per million by volume
Authority for Requirement: 567 IAC 23.3(3)"e"

Particulate Matter:

No person shall cause or allow the emission of particulate matter from any source in excess of the emission standards specified in this chapter, except as provided in 567 – Chapter 24. For sources constructed, modified or reconstructed on or after July 21, 1999, the emission of particulate matter from any process shall not exceed an emission standard of 0.1 grain per dry standard cubic foot of exhaust gas, except as provided in 567 – 21.2(455B), 23.1(455B), 23.4(455B) and 567 – Chapter 24.

For sources constructed, modified or reconstructed prior to July 21, 1999, the emission of particulate matter from any process shall not exceed the amount determined from Table I, or amount specified in a permit if based on an emission standard of 0.1 grain per standard cubic foot of exhaust gas or established from standards provided in 23.1(455B) and 23.4(455B).
Authority for Requirement: 567 IAC 23.3(2)"a"

Fugitive Dust: Attainment and Unclassified Areas - A person shall take reasonable precautions to prevent particulate matter from becoming airborne in quantities sufficient to cause a nuisance as defined in Iowa Code section 657.1 when the person allows, causes or permits any materials to be

handled, transported or stored or a building, its appurtenances or a construction haul road to be used, constructed, altered, repaired or demolished, with the exception of farming operations or dust generated by ordinary travel on unpaved roads. Ordinary travel includes routine traffic and road maintenance activities such as scarifying, compacting, transporting road maintenance surfacing material, and scraping of the unpaved public road surface. (the preceding sentence is State Only) All persons, with the above exceptions, shall take reasonable precautions to prevent the discharge of visible emissions of fugitive dusts beyond the lot line of the property on which the emissions originate. The public highway authority shall be responsible for taking corrective action in those cases where said authority has received complaints of or has actual knowledge of dust conditions which require abatement pursuant to this subrule. Reasonable precautions may include, but not be limited to, the following procedures.

1. Use, where practical, of water or chemicals for control of dusts in the demolition of existing buildings or structures, construction operations, the grading of roads or the clearing of land.
2. Application of suitable materials, such as but not limited to asphalt, oil, water or chemicals on unpaved roads, material stockpiles, race tracks and other surfaces which can give rise to airborne dusts.
3. Installation and use of containment or control equipment, to enclose or otherwise limit the emissions resulting from the handling and transfer of dusty materials, such as but not limited to grain, fertilizer or limestone.
4. Covering, at all times when in motion, open-bodied vehicles transporting materials likely to give rise to airborne dusts.
5. Prompt removal of earth or other material from paved streets or to which earth or other material has been transported by trucking or earth-moving equipment, erosion by water or other means.
6. Reducing the speed of vehicles traveling over on-property surfaces as necessary to minimize the generation of airborne dusts.

Authority for Requirement: 567 IAC 23.3(2)"c"

Facility Wide Requirements

All equipment located at the facility shall comply with the following requirements. These requirements do apply to a number of pieces of equipment that are not subject to Title V permitting. The facility shall consider emissions from all equipment when certifying compliance on the Annual Compliance Certification and Semi-Annual Monitoring Reports.

Emission Limits

Pollutant: Volatile Organic Compounds (VOC)

Emission Limit(s): 98 tons/yr.

Authority for Requirement: DNR Construction Permits 95-A-445-S22, 12-A-561-S2, 13-A-176-S2, 14-A-626-S2, 19-A-067

Pollutant: Single Hazardous Air Pollutant (HAP)

Emission Limit(s): 9.4 tons/yr.

Authority for Requirement: DNR Construction Permits 95-A-445-S22, 12-A-561-S2, 13-A-176-S2, 14-A-626-S2, 19-A-067

Pollutant: Total Hazardous Air Pollutant (HAP)

Emission Limit(s): 24.4 tons/yr.

Authority for Requirement: DNR Construction Permits 95-A-445-S22, 12-A-561-S2, 13-A-176-S2, 14-A-626-S2, 19-A-067

VOC Emissions Limit Requirements

The facility wide VOC emission limit calculations for construction permits 95-A-445-S22 and 14-A-626-S2 differ from those found in 12-A-561-S2, 13-A-176-S2 and 19-A-067. Please refer to the conditions for each emission point (construction permit) for demonstrating compliance with the facility wide VOC emission limit.

Single HAP Emissions Limit Requirements

The facility wide Single HAP emission limit calculations for construction permits 95-A-445-S22 and 14-A-626-S2 differ from those found in 12-A-561-S2, 13-A-176-S2 and 19-A-067. Please refer to the conditions for each emission point (construction permit) for demonstrating compliance with the facility wide Single HAP emission limit.

Total HAP Emissions Limit Requirements

The facility wide Total HAP emission limit calculations for construction permits 95-A-445-S22 and 14-A-626-S2 differ from those found in 12-A-561-S2, 13-A-176-S2 and 19-A-067. Please refer to the conditions for each emission point (construction permit) for demonstrating compliance with the facility wide Total HAP emission limit.

VOC And HAP Emissions Reporting Requirements

Please refer to the conditions for each emission point (construction permit) for demonstrating compliance with the facility wide VOC and HAP emissions reporting

Authority for Requirement: DNR Construction Permits 95-A-445-S22, 12-A-561-S2, 13-A-176-S2, 14-A-626-S2, 19-A-067

NESHAP Requirements:

The requirements of 40 CFR 63 Subpart VVVVVV - National Emission Standards for Hazardous Air Pollutants for Chemical Manufacturing Area Sources are applicable to the equipment listed in this Title V permit while producing a chemical subject to this Subpart. The following are the Subpart VVVVVV requirements for affected Chemical Manufacturing Process Units (CMPU).

Applicable management practices 63.11495"a"(1), (3), (4), (5) & "b"(1), (2), (3) while in Subpart VVVVVV service, specifically:

Standard	Operational or Emission Limit			
40 CFR 63.11495(a)(1)	Each process vessel must be equipped with a cover or lid that must be closed at all times when it is in organic HAP service, except for manual operations that require access, such as material addition and removal, inspection, sampling and cleaning.			
40 CFR 63.11495(a)(3)	For these inspections, detection methods incorporating sight, sound, or smell are acceptable. Indications of a leak identified using such methods constitute a leak unless you demonstrate that the indications of a leak are due to a condition other than loss of HAP. If	AND Inspections must be conducted while the subject CMPU is operating.	AND No inspection is required in a calendar quarter during which the subject CMPU does not operate for the entire calendar quarter and is not in organic HAP service or metal HAP service. If the	AND You must repair any leak within 15 calendar days after detection of the leak, or document the reason for any delay of repair. For the purposes of this paragraph (a)(4), a leak will be

	indications of a leak are determined not to be HAP in one quarterly monitoring period, you must still perform the inspection and demonstration in the next quarterly monitoring period		CMPU operates at all during a calendar quarter, an inspection is required.	considered "repaired" if a condition specified in paragraph (a)(4)(i), (ii), or (iii) of this section is met. (i) The visual, audible, olfactory, or other indications of a leak to the atmosphere have been eliminated, or (ii) No bubbles are observed at potential leak sites during a leak check using soap solution, or (iii) The system will hold a test pressure.
40 CFR 63.11495(b)	Small heat exchange systems. For each heat exchange system subject to this subpart with a cooling water flow rate less than 8,000 gallons per minute (gal/min) and not meeting one or more of the conditions in § 63.104(a), you must comply with paragraphs (b)(1) through (3) of this section.	The owner or operator must develop and operate in accordance with a heat exchange system inspection plan. The plan must describe the inspections to be performed that will provide evidence of hydrocarbons in the cooling water. Among other things, inspections may include checks for visible floating hydrocarbon on the water, hydrocarbon odor, discolored water, and/or chemical addition rates. You	The owner or operator must perform repairs to eliminate the leak and any indications of a leak or demonstrate that the HAP concentration in the cooling water does not constitute a leak, as defined by § 63.104(b)(6), within 45 calendar days after indications of	

		must conduct inspections at least once per quarter, even if the previous inspection determined that the indications of a leak did not constitute a leak as defined by § 63.104(b)(6).	the leak are identified, or you must document the reason for any delay of repair in your next semiannual compliance report.	
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General Duty requirements 63.11495"d", specifically:

Standard	Operational or Emission Limit			
40 CFR 63.11495(d)	At all times, The owner or operator must operate and maintain any affected CMPU, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions.			

Calculating uncontrolled Organic HAP emissions from batch process vents 63.11496"a" and "d" while in Subpart VVVVVV service, specifically:

Standard	Operational or Emission Limit			
40 CFR 63.11496(a)	The owner or operator must determine the sum of actual organic HAP emissions from all of your batch process vents within a CMPU subject to this subpart using process knowledge, engineering assessment, or test data. Emissions for a			

	standard batch in a process may be used to represent actual emissions from each batch in that process.			
40 CFR 63.11496(d)	Halogenated streams. You must determine if an emission stream is a halogenated vent stream by calculating the mass emission rate of halogen atoms in accordance with §63.115(d)(2)(v).	Alternatively, you may elect to designate the emission stream as halogenated.		

Wastewater requirements 63.11498 while in Subpart VVVVVV service, specifically:

Standard	Operational or Emission Limit			
40 CFR 63.11498(a)(1)	The owner or operator must determine the total concentration of partially soluble HAP in each wastewater stream using process knowledge, engineering assessment, or test data.	Also, you must reevaluate the concentration of partially soluble HAP if you make any process or operational change that affects the concentration of partially soluble HAP in a wastewater stream.		

Notification, recordkeeping, and reporting requirements 63.11501, specifically:

Standard	Operational or Emission Limit			
40 CFR 63.11501	You must submit semiannual compliance reports that contain the information specified in paragraphs (d)(1) through (7) of this section, as applicable.	AND Reports are required only for semiannual periods during which you experienced any of the events described in paragraphs (d)(1) through (8) of this section.		

Additional, equipment-specific Subpart VVVVVV requirements are provided in Section III.

Authority for Requirement: 40 CFR 63 Subpart VVVVVV
567 IAC 23.1(4)"ev"

III. Emission Point-Specific Conditions

Facility Name: Cambrex Charles City, Inc.

Permit Number: **15-TV-007R1-M001**

Emission Point ID Number: EP 303

Associated Equipment

Emission Unit	Emission Unit Description	Control Equipment	Raw Material	Construction Permit
Various	Pharma I Production	C-3109: Main Scrubber	Pharmaceutical Raw Materials	95-A-445-S22

Please see Appendix A for the total list of equipment associated with this emission point.

Applicable Requirements

Emission Limits (lb./hr, gr./dscf, lb./MMBtu, % opacity, etc.)

The emissions from this emission point shall not exceed the levels specified below.

Pollutant: Opacity

Emission Limit(s): 40%⁽¹⁾

Authority for Requirement: DNR Construction Permit 95-A-445-S22
567 IAC 23.3(2)"d"

⁽¹⁾ An exceedance of the indicator opacity of 10% will require the owner or operator to promptly investigate the emission unit and make corrections to operations or equipment associated with the exceedance. If exceedances continue after the corrections, the Department may require additional proof to demonstrate compliance (e.g., stack testing).

Pollutant: Particulate Matter (PM₁₀)

Emission Limit(s): 1.03 lb/hr.

Authority for Requirement: DNR Construction Permit 95-A-445-S22

Pollutant: Particulate Matter

Emission Limit(s): 1.03 lb/hr., 0.1 gr/dscf

Authority for Requirement: DNR Construction Permit 95-A-445-S22
567 IAC 23.3(2)"a"

Pollutant: Sulfur Dioxide (SO₂)

Emission Limit(s): 0.67 lb/hr, 500 ppmv

Authority for Requirement: DNR Construction Permit 95-A-445-S22
567 IAC 23.3(3)"e"

Pollutant: Carbon Monoxide
 Emission Limit(s): 1.17 lb/hr
 Authority for Requirement: DNR Construction Permit 95-A-445-S22

Pollutant: Volatile Organic Compounds
 Emission Limit(s): See Plant-Wide Conditions
 Authority for Requirement: DNR Construction Permit 95-A-445-S22

Pollutant: Single Hazardous Air Pollutants (HAPs)
 Emission Limit(s): 9.4 tons/yr
 Authority for Requirement: DNR Construction Permit 95-A-445-S22

Pollutant: Total Hazardous Air Pollutants (HAPs)
 Emission Limit(s): 24.4 tons/yr
 Authority for Requirement: DNR Construction Permit 95-A-445-S22

NSPS and NESHAP Applicability

Tank T-1232 is subject to Subparts A (*General Provisions*; 40 CFR §60.1 – 40 CFR §60.19) and Kb [*Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984*; 40 CFR §60.110b – 40 CFR §60.117b] of the New Source Performance Standards (NSPS).

The requirements of 40 CFR 63 Subpart VVVVVV - National Emission Standards for Hazardous Air Pollutants for Chemical Manufacturing Area Sources are applicable to the equipment listed in this Title V permit while producing a chemical subject to this Subpart. The following are the equipment-specific Subpart VVVVVV requirements. Also subject to 40 CFR 63 Subpart A (General Provisions; 40 CFR §63.1 – 40 CFR §63.16)

Applicable control requirements 63.11496"a" and Table 2, while in Subpart VVVVVV operation, specifically:

Standard	Operational or Emission Limit	
40 CFR 63.11496(a) and Table 2	You must comply with the requirements in paragraphs (a)(1) through (4) of this section for organic HAP emissions from your batch process vents for each CMPU using Table 1 organic HAP. If uncontrolled organic HAP emissions from all batch process vents from a CMPU subject to this subpart are equal to or greater than 10,000 pounds per year (lb/yr), you must also comply with the emission limits and other requirements in Table 2 to this subpart.	Table 2 (1)a. Reduce collective uncontrolled total organic HAP emissions from the sum of all batch process vents by ≥ 85 percent by weight or to ≤ 20 ppmv by routing emissions from a sufficient number of the batch process vents through a closed vent system to any combination of control devices (except a flare) in accordance with the requirements of §63.982(c) and the requirements referenced therein

Authority for Requirement: 40 CFR 60 Subpart A
567 IAC 23.1(2)
40 CFR 60 Subpart Kb
567 IAC 23.1(2)"ddd"
40 CFR 63 Subpart A
567 IAC 23.1(4)
40 CFR 63 Subpart VVVVVV
567 IAC 23.1(4)"ev"
DNR Construction Permit 95-A-445-S22

Operating Requirements with Associated Monitoring and Recordkeeping

All records as required by this permit shall be kept on-site for a minimum of five (5) years and shall be available for inspection by the Department. Records shall be legible and maintained in an orderly manner. The operating requirements and associated recordkeeping for this permit shall be:

- A. The process equipment¹ covered by this permit may exhaust through several permitted emission points (controlled or uncontrolled).
 - i. The owner or operator shall maintain records on the identification of the equipment and the associated emission point.

NSPS and NESHAP REQUIREMENTS (PHARMA 1, EP-303)

- B. The owner or operator shall comply with the applicable requirements in 40 CFR Part 60, Subpart Kb [§60.110b – §60.117b], including those not specifically mentioned in this permit.
 - i. Per 40 CFR §60.116b(b), the owner or operator shall keep readily accessible records showing the dimension of Tank T-1232 and an analysis showing the capacity of this vessel. These records shall be kept on-site for the life of the unit.
 - ii. The maximum true vapor pressure, as defined in 40 CFR §60.111b, of the volatile organic liquid (VOL) as defined in §60.111b, stored in Tank T-1232 shall be less than 27.6 kilopascals (kPa).
 - 1. Per 40 CFR §60.116b(c), the owner or operator shall maintain a record of the VOL stored, the period of storage, and the maximum true vapor pressure of that VOL during the respective storage period for Tank T-1232.
 - 2. Per 40 CFR §60.116b(d), the owner or operator shall notify the Department within 30 days when the maximum true vapor pressure of the liquid stored in Tank T-1232 exceeds 27.6 kPa.
- C. The owner or operator shall comply with the applicable requirements in 40 CFR Part 63, Subpart VVVVVV §63.11494 – §63.11502], including those not specifically mentioned in this permit.
 - i. The owner or operator shall comply with the applicable management practices as set forth in §63.11495 of Subpart VVVVVV, including, but not limited to:
 - 1. Equip each process vessel with a cover or lid that shall always be

¹ Process equipment may include, but it is not limited to centrifuges, columns, dryers, evaporators, process tanks, reactors, and vacuum pump systems.

- closed when it is in HAP service, except for manual operations that require access, such as material addition and removal, inspection, sampling, and cleaning.
2. Control total organic HAP emissions from transfer of liquids containing Table 1 organic HAP to tank trucks or railcars using any of the methods listed in §63.11495(a)(2)(i) through (iv).
 3. Conduct inspections of process vessels and equipment for each chemical manufacturing process unit (CMPU)¹ in HAP service, as specified in §63.11495(a)(3)(i) through (v).
 4. Repair any leak with 15 calendar days after detection of the leak or document the reason for any delay of repair. A leak shall be considered “repaired” if a condition specified in §63.11495(a)(4)(i), (ii) or (iii) is met.
 5. Keep records of the dates and results of each inspection event, the dates of equipment repairs, and, if applicable, the reasons for any delay in repair.
- ii. The owner or operator shall comply with the applicable standards and compliance requirements for batch process vents as set forth in §63.11496 of Subpart VVVVVV, including, but not limited to:
1. Demonstrate compliance with the requirements in §63.11496(a)(1) through (4) for organic HAP emissions from each batch process at the Pharma 1 Production Facility using Table 1 organic HAP.
 2. Demonstrate compliance with the emission limits and other requirements in Table 2 to Subpart VVVVVV if uncontrolled organic HAP emissions from all batch process vents from a CMPU at the Pharma 1 Production Facility are equal to or greater than 10,000 pounds per year.
- iii. The owner or operator shall comply with the applicable standards and compliance requirements for wastewater systems as set forth in §63.11498 of Subpart VVVVVV, including, but not limited to:
1. Demonstrate compliance with the applicable requirements in §63.11498(a) and in Table 6 for all wastewater streams at the Pharma 1 Production Facility subject to Subpart VVVVVV.
 2. Determine the total concentration of partially soluble HAP in each wastewater stream using process knowledge, engineering assessment, or test data.
 - a) If the owner or operator makes any process or operational change that affects the concentration of partially soluble HAP in a wastewater stream, the concentration of partially soluble HAP shall be reevaluated.

¹ Per 40 CFR §63.11502, a CMPU means “all equipment which collectively functions to produce a product or isolated intermediate. A process includes, but it is not limited to any, all, or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a product or isolated intermediate.”

- iv. The owner or operator shall comply with the applicable notification, recordkeeping, and reporting requirements as set forth in §63.11501 of Subpart VVVVVV.

VOC and HAP EMISSIONS CALCULATIONS REQUIREMENTS (PHARMA 1, EP-303)

- D. The owner or operator shall determine uncontrolled VOC and HAP emission rates from the process equipment covered by this permit by using one of the following methods:
 - i. The owner or operator shall use the appropriate equations in 40 CFR §63.1257(d)(2)(i) of Subpart GGG (*National Emission Standards for Pharmaceuticals Production*) to determine emissions from pharmaceutical production episodes such as displacement, purging, heating, depressurization, gas evolution, air drying, and empty vessel purging.
 - ii. The owner or operator shall use the appropriate estimation methods in 40 CFR §63.1257(d)(2)(ii) of Subpart GGG (*National Emission Standards for Pharmaceuticals Production*) to determine emissions from other pharmaceutical production episodes.
 - iii. The owner or operator shall use appropriate resources, including “Methods for Estimating Air Emissions from Chemical Manufacturing Facilities” and the “pharmaceutical MACT” to determine emissions from non-pharmaceutical production.
 - iv. Where no U.S. EPA emission calculations are applicable, the owner or operator shall use standard engineering principles to best represent emissions from non-pharmaceutical production.
- E. The owner or operator shall develop and document uncontrolled VOC emission factors (Ef_{VOC}), in pounds of VOC per pound of product and uncontrolled Single HAP emission factors (Ef_{SHAP}), in pounds of Single HAP per pound of product, to determine VOC and HAP emissions from the operation of the process equipment covered by this permit, including emissions from equipment leaks.
 - i. The calculation of each emission factor shall be subject to the review and approval of the Department. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, during the production of a specific final product to confirm the accuracy of the emission factor.
- F. The owner or operator shall maintain the following monthly records for each batch run in the process equipment covered by this permit:
 - i. The identification and amount (gallons or pounds) of all materials used in the development of the emission factors for determining the emission rates from the process equipment covered by this permit.
 - ii. The identification and quantity of each final product generated.
- G. The owner or operator shall maintain monthly records of the controlled VOC and HAP emission rates for each batch of chemicals processed in the process equipment covered by this permit.
 - i. The owner or operator shall determine the controlled vent emission rates by using the applicable control efficiencies described in Construction Permit Conditions 5a.S.ii, 5a.T.ii, and 5a.U.
- H. The owner or operator shall use the appropriate equations and methods in EPA’s most recent Chapter 7 of EPA’s AP-42 (Compilation of Air Pollution Emission Factors) to

determine uncontrolled VOC and HAP emissions from the storage tanks covered by this permit.

- I. The owner or operator shall maintain the following monthly records:
 - i. Solvent throughput, in gallons, for each storage tank covered by this permit that operated each month.
 - ii. Liquid level for each storage tank covered by this permit that operated that month. If level data is not available, the owner or operator may assume maximum headspace and monthly throughput.
 - iii. Controlled VOC and HAP emission rates from each storage tank covered by this permit that operated each month.
 1. The owner or operator shall determine the controlled vent emission rates by using the applicable control efficiencies described in Construction Permit Conditions 5a.S.ii, 5a.T.ii, and 5a.U.
- J. The owner shall calculate monthly VOC emissions, in tons, emitted from the process equipment and storage tanks covered by this permit using the following equation:

Monthly VOC Emissions:

$$\text{VOC}_{\text{Month(EP-303)}} = \sum [\{ (\text{Ef}_{\text{VOC}} \times \text{PP}_{\text{Month}}) + (\text{Storage Tank VOC Emissions}) \} * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable CE})]$$

Where:

$\text{VOC}_{\text{Month(EP-303)}}$ = Total tons of VOC emitted each month through EP-303

Ef_{VOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP_{Month} = Pounds of each product generated per process each month

Storage Tank VOC Emissions = Breathing and working VOC losses from each storage tank, determined using the appropriate equations and methods in EPA's most recent Chapter 7 of EPA's AP-42 (Compilation of Air Pollution Emission Factors)

(1 - Applicable CE) = [(Efficiency of the control equipment as specified in Construction Permit Conditions 5a.S.ii, 5a.T.ii, and 5a.U.)]

- K. The owner or operator shall record the total monthly ($\text{VOC}_{\text{Month(EP-303)}}$) VOC emissions, in tons, from the operation of the process equipment and storage tanks covered by this permit.
- L. The owner or operator shall calculate monthly emissions, in tons, for each Single HAP emitted from the process equipment and storage tanks covered by this permit using the following equation:

Monthly Single HAP Emissions:

$$\text{SHAP}_{\text{Month(EP-303)}} = \sum [\{ (\text{Ef}_{\text{SHAP}} \times \text{PP}_{\text{Month}}) + (\text{Storage Tank SHAP Emissions}) \} * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable CE})]$$

Where:

$\text{SHAP}_{\text{Month(EP-303)}}$ = Total tons of Single HAP (SHAP) emitted each month through EP-303

Ef_{SHAP} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Month} = Pounds of each product generated per process each month

Storage Tank SHAP Emissions = Breathing and working SHAP losses from each storage tank, determined using the appropriate equations and methods in EPA's most recent Chapter 7 of EPA's AP-42 (Compilation of Air Pollution Emission Factors)

(1 - Applicable CE) = [(Efficiency of the control equipment as specified in Construction Permit Conditions 5a.S.ii, 5a.T.ii, and 5a.U)]

- M. The owner or operator shall record the monthly ($SHAP_{Month(EP-303)}$) emissions, in tons, for each Single HAP (SHAP) from the operation of the process equipment and storage tanks covered by this permit.
- N. The owner or operator shall calculate monthly Total HAP emissions, in tons, emitted from the process equipment and storage tanks covered by this permit using the following equation:

Monthly Total HAP Emissions:

$$THAP_{Month(EP-303)} = \sum (Monthly \text{ Emissions } \left(\frac{tons}{month} \right) \text{ for each Single HAP})$$

Where:

$THAP_{Month(EP-303)}$ = Total tons of Total HAP emitted each month through EP-303

- O. The owner or operator shall record the total monthly ($THAP_{Month(EP-303)}$) Total HAP emissions, in tons, from the operation of the process equipment and storage tanks covered by this permit.

CONTROL EQUIPMENT REQUIREMENTS (PHARMA 1, EP-303)

- P. The owner or operator shall operate Pharma 1 Main Scrubber (C-3109) whenever any of the equipment described in Construction Permit Condition 3b is active, except during maintenance activities.
 - i. When active, the equipment described in Construction Permit Condition 3b may use any number of the control equipment described below prior to exhausting to the Pharma 1 Main Scrubber (C-3109).
 - 1. Three (3) EST Venturi Scrubbers (C-3111, C-3602, and C-6020)
 - 2. Pfaudler Condenser, Model 08-090-BEM (VS-3760-H-6050)
 - 3. Vapor Phase Carbon Adsorption Unit (C-3106)
 - 4. Vapor Condensers (H-3110A, H-3110B). H-3110A and H-3110B, each consists of two condensers: a glycol condenser followed by a cryogenic condenser. If used, normally one condenser train will be operated.
 - 5. Venturi Scrubber (C-3118) for acid vapor control.
 - ii. During the Pharma 1 Main Scrubber (C-3109) maintenance activities, the owner or operator shall:
 - 1. Place all inactive process equipment and storage tanks in "maintenance hold" to limit emissions.
 - 2. Record the time and date at which maintenance began.
 - 3. Record the time and date at which maintenance ended.

4. Record total hours of Pharma 1 Main Scrubber (C-3109) downtime.
 5. Calculate and record uncontrolled breathing losses¹ from the storage tanks that occur during the maintenance period.
 6. Include storage tank breathing losses in the applicable monthly total of VOC and HAP emissions.
- Q. Equipment in in Partially Soluble HAP service may exhaust through the carbon adsorption unit, C-3106, or the vapor condensers H-3110A or H-3110B, then to the Pharma 1 Main Scrubber (C-3109).
- R. The Vapor Phase Carbon Adsorption Unit (C-3106) shall have a minimum control efficiency of 95 percent. This control efficiency is based on the manufacturer's design specifications and performance data. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, to verify the minimum control efficiency of the Vapor Phase Carbon Adsorption Unit (C-3106).
- i. The owner or operator shall operate and maintain the ionization detectors that service the Vapor Phase Carbon Adsorption Unit (C-3106) according to manufacturer's specifications and instructions.
 - ii. For VOC and HAP emissions controlled by the Vapor Phase Carbon Adsorption Unit (C-3106), the owner or operator shall multiply the uncontrolled emission rate (see Construction Permit Conditions 5a.D and 5a.H) by $(1 - 0.95)$, where 0.95 represents the minimum control efficiency of the Vapor Phase Carbon Adsorption Unit (C-3106).
- S. The Vapor Condensers (H-3110A, H-3110B) shall have a minimum control efficiency of 95 percent. This control efficiency is based on the manufacturer's design specifications and performance data. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, to verify the minimum control efficiency of the Vapor Condensers (H-3110A, H-3110B).
- i. The owner or operator shall maintain the average daily exhaust temperature after the final condenser at or below -47 degrees Celsius.
 1. The owner or operator shall install, operate, and maintain equipment capable of providing a continuous record of the temperature when the condensers are in operation. This equipment shall be installed, operated, and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.
 2. The owner or operator shall collect and record the final condenser average daily exhaust temperature, in degrees Celsius.
 3. If the daily average temperature exceeds the minimum required value, the owner or operator shall record the time, date, and actions taken to correct the situation and shall record when the average temperature is back at or below the minimum required value.
 4. These requirements shall not apply during periods when the applicable condenser or the equipment that the applicable condenser controls is not in operation.
 - ii. For VOC and HAP emissions controlled by the Vapor Condensers (H-3110A, H-3110B), the owner or operator shall multiply the uncontrolled emission rate (see

¹ During maintenance activities, breathing losses from the outdoor storage tanks may occur as they warm over the day.

Construction Permit Conditions 5a.D and 5a.H) by $(1 - 0.95)$, where 0.95 represents the minimum control efficiency of the Vapor Condensers (H-3110A, H-3110B).

T. The control efficiency requirements for the Pharma 1 Main Scrubber (C-3109) are as follows:

- i. For water soluble organic HAPs or VOC, the owner or operator shall multiply the uncontrolled emission rate (see Construction Permit Conditions 5a.D and 5a.H) by $(1 - 0.95)$, where 0.95 represents the minimum control efficiency of the scrubber. This control efficiency is based on the manufacturer's design specifications and performance data. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, to verify the minimum control efficiency of the scrubber.
- ii. For inorganic acidic HAP emissions or SO_2 emissions the owner or operator shall multiply the uncontrolled emission rate (see Construction Permit Conditions 5a.D and 5a.H) by $(1 - 0.98)$, where 0.98 represents the minimum control efficiency of the scrubber. This control efficiency is based on the manufacturer's design specifications and performance data. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, to verify the minimum control efficiency of the scrubber.
- iii. For other HAPs and VOCs, the solubility of the pollutant in the respective scrubber media shall be used to determine the removal efficiency of the scrubber. This allows to take into consideration the reduced control efficiency due to the insolubility of certain air contaminants in the scrubbing media. Therefore, the owner or operator shall multiply the uncontrolled emission rate (see Construction Permit Conditions 5a.D and 5a.H) by $(1 - x)$, where x represents the control efficiency of the scrubber for the air contaminant as determined by its solubility in the scrubber media. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, to verify the control efficiency of the scrubber.

U. The water flow rate requirements for the Pharma 1 Main Scrubber (C-3109) are as follows:

- i. The owner or operator shall maintain a 24-hour rolling average Pharma 1 Main Scrubber water flow rate at or above 42 gallons per minute.
 1. The owner or operator shall install, operate, and maintain equipment capable of providing a continuous record of the Pharma 1 Main Scrubber (C-3109) water flow rate. This equipment shall be installed, operated, and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.
 2. The owner or operator shall collect and record the 24-hour rolling water flow rate average, in gallons per minute, for the Pharma 1 Main Scrubber (C-3109).
 3. If the 24-hour rolling average water flow rate falls below the minimum required value, the owner or operator shall record the time, date, and actions taken to correct the situation and shall record when the average water flow rate is back at or above the minimum required value.
 4. These requirements shall not apply during periods when the Pharma 1

Main Scrubber (C-3109) or the equipment that this scrubber controls is not in operation.

- V. The pH requirements for the Pharma 1 Main Scrubber (C-3109) are as follows:
- i. When the process equipment can emit acid gases, the owner or operator shall maintain the scrubber liquor pH within the range required by the manufacturer.
 1. The owner or operator shall install, operate, and maintain equipment necessary to monitor the scrubber liquor pH on a daily basis. This equipment shall be installed, operated, and maintained in accordance with the manufacturer's specifications.
 2. If the scrubber liquor pH falls outside the required range, the owner or operator shall record the time, date, and actions taken to correct the situation and shall record when the average pH value is back within the required range.
 3. These requirements shall not apply during periods when the applicable scrubber or the equipment that it controls is not in operation.
- W. The owner or operator shall operate, inspect, and maintain the control equipment associated with the Pharma 1 Production Facility according to the manufacturer's specifications and instructions.
- X. The owner or operator shall install, calibrate, and maintain an automated system that uses audible and visual alarms to warn of the Pharma 1 Main Scrubber (C-3109) malfunctions.
- Y. The owner or operator shall keep a record all maintenance and inspection activities performed on the control equipment, ionization detectors, and monitoring devices. At a minimum, this record shall include any issues identified during inspection and maintenance activities and the date each issue was resolved.

FACILITY-WIDE GENERAL REQUIREMENTS

- A. The facility-wide emission limits (VOC, Single HAP, and Total HAP) listed in Construction Permit Condition 1 shall apply to all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015.
- B. The owner or operator shall determine uncontrolled VOC and HAP emission rates from all the process equipment operating (including emissions from equipment leaks) at Plant No. 34-01-015 by using one of the following methods:
- i. The owner or operator shall use the appropriate equations in 40 CFR §63.1257(d)(2)(i) of Subpart GGG (*National Emission Standards for Pharmaceuticals Production*) to determine emissions from pharmaceutical production episodes such as displacement, purging, heating, depressurization, gas evolution, air drying, and empty vessel purging.
 - ii. The owner or operator shall use the appropriate estimation methods in 40 CFR §63.1257(d)(2)(ii) of Subpart GGG (*National Emission Standards for Pharmaceuticals Production*) to determine emissions from other pharmaceutical production episodes.
 - iii. The owner or operator shall use appropriate resources, including "Methods for Estimating Air Emissions from Chemical Manufacturing Facilities" and the "pharmaceutical MACT" to determine emissions from non-pharmaceutical

- production.
- iv. Where no U.S. EPA emission calculations are applicable, the owner or operator shall use standard engineering principles to best represent emissions from non-pharmaceutical production.
- C. The owner or operator shall develop and document uncontrolled VOC emission factors (E_{fVOC}), in pounds of VOC per pound of product and uncontrolled Single HAP emission factors (E_{fSHAP}), in pounds of Single HAP per pound of product, to determine VOC and HAP emissions from the operation of each process equipment operating at Plant No. 34-01-015, including all emissions from equipment leaks.
- ii. The calculation of each emission factor shall be subject to the review and approval of the Department. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, during the production of a specific final product to confirm the accuracy of the emission factor.
- D. The owner or operator shall maintain the following monthly records for each batch run in every process equipment operating at Plant No. 34-01-015:
- i. The identification and amount (gallons or pounds) of all materials used in the development of the emission factors for determining the emission rates from each process equipment operating at Plant No. 34-01-015.
 - ii. The identification and quantity of each final product generated.
- E. The owner or operator shall maintain monthly records of the controlled VOC and HAP emission rates for each batch of chemicals processed in each process equipment operating at Plant No. 34-01-015.
- i. The owner or operator shall determine the controlled vent emission rates by using the applicable control efficiencies described in each applicable construction permit.
- F. The owner or operator shall use the appropriate equations and methods in EPA's most recent Chapter 7 of EPA's AP-42 (Compilation of Air Pollution Emission Factors) to determine uncontrolled VOC and HAP emissions from each storage tank operating at Plant No. 34-01-15.
- G. The owner or operator shall maintain monthly records as described in the permits issued to the wastewater treatment plant, the boilers, and the non-emergency generators, respectively.

FACILITY-WIDE VOC EMISSIONS LIMIT REQUIREMENTS

- H. The total amount of VOC emitted from all the chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall not exceed 98 tons in any 12-month rolling period.
- i. The owner or operator shall calculate the total amount, in tons, of VOC emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant Number 34-01-015 using the following equation:

$$\text{VOC}_{(\text{Facility})} = \text{VOC}_{(\text{Chem})} + \text{VOC}_{(\text{Storage})} + \text{VOC}_{(\text{WWTP})} + \text{VOC}_{(\text{Boilers})} + \text{VOC}_{(\text{Gen})}$$

Where:

$\text{VOC}_{(\text{Facility})}$ = Total tons of VOC emitted at Plant No. 34-01-015

$\text{VOC}_{(\text{Chem})} = \sum[(\text{Ef}_{\text{VOC}} \times \text{PP}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$

Where,

$\text{VOC}_{(\text{Chem})}$ = Total tons of VOC emitted from all the chemical

processes (including emissions from equipment leaks) at Plant No. 34-01-015

Ef_{VOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP = Pounds of each product generated per process

Applicable Control Efficiency = [(Percent efficiency of the control equipment listed in the construction permit for the emission point) / 100] (Zero for process steps with no control)

$\text{VOC}_{(\text{Storage})}$ = Total tons of VOC emitted from all the storage tanks at Plant No. 34-01-015 as determined using the most recent Chapter 7 of EPA's AP-42

$\text{VOC}_{(\text{WWTP})}$ = Total tons of VOC emitted from the wastewater treatment plant as determined using the procedures in the permit.

$\text{VOC}_{(\text{Boilers})}$ = Total tons of VOC emitted from the boilers as determined using the procedures in each applicable permit

$\text{VOC}_{(\text{Gen})}$ = Total tons of VOC emitted from the non-emergency generators using the procedures in each applicable permit.

- ii. The owner or operator shall record the total monthly amount, in tons, of VOC emitted from all chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015. The owner or operator shall calculate the total monthly VOC emissions using the equation in Construction Permit Condition 5b.H.i.
- iii. The owner or operator shall calculate and record the total amount, in tons, of VOC emitted from all chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015 on a rolling 12-month basis.
- I. If the 12-month rolling total amount of VOC emitted at Plant Number 34-01-015 exceeds 78.4 tons, the owner or operator shall immediately begin calculating daily VOC emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency

generators at Plant Number 34-01-015.

- i. The following requirements apply to the daily VOC emissions calculations associated with the chemical processes (including emissions from equipment leaks) at Plant Number 34-01-015.
 1. The owner or operator may use the facility's emission inventory software (Emissions Accountant) to establish the daily emissions for the 12-month rolling period preceding the onset of daily emission recordkeeping.
 - a) The daily emission data for the previous 12 months (prior to onset) shall be an average of the monthly production data input to the facility's emissions accounting data system.
 2. The owner or operator shall maintain the following records:
 - a) The identification and quantity (pounds) of each product scheduled to be generated during each calendar year and the corresponding VOC emissions, in tons.
 - b) The projected total amount of VOC emissions for each product, in tons.
 - c) The projected total amount of VOC emissions for all products combined, in tons.
 3. The projected emissions totals shall be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors shall be added once their respective batch record is finalized.
 4. Projected emissions shall be totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The owner or operator shall enter the actual production data within 15 days of batch completion.
- ii. The following requirements apply to the daily VOC emissions calculations from the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015.
 1. The owner or operator shall assume the worst-case scenario for each source, i.e., the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators, based on data from the available 12-month period preceding the onset of daily emission recordkeeping.
 - a) The daily emission data for the previous 12 months (prior to onset) shall be the worst-case monthly emission values for each source averaged over the days in that month.
 - (1) The owner or operator shall determine the worst-case monthly emission values for the wastewater treatment plant, the boilers, and the non-emergency generators using the month with the highest combined VOC emissions.
 - (2) The owner or operator shall determine the worst-case monthly emission values for the storage tanks on a tank-by-tank basis.
 2. After each respective month is completed, the actual emissions will supersede the projected emissions. The actual daily emissions shall be calculated by averaging the actual emissions from that month for each

source, using the procedures in each applicable permit, over the days in that month. The owner or operator shall enter the actual emissions data within 15 days of the end of the month.

- iii. The owner or operator shall record the total daily amount, in tons, of VOC emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015. The owner or operator shall calculate total daily VOC emissions using the equation in Construction Permit Condition 5b.H.i.
- iv. The owner or operator shall revise the daily VOC emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators when monthly emission data is available.
- v. Daily emission calculations and recordkeeping of VOC emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall continue until the rolling 12-month total VOC emissions from the facility drops below 78.4 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of VOC emissions from these sources shall cease.

FACILITY-WIDE SINGLE HAP EMISSIONS LIMIT REQUIREMENTS

- J. The total amount of each Single HAP (SHAP) emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, wastewater treatment plant, boilers, and non-emergency generators operating at Plant No. 34-01-015 shall not exceed 9.4 tons in any 12-month rolling period.

- i. The owner or operator shall calculate the total amount, in tons, of each SHAP emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 using the following equation:

$$SHAP_{(Facility)} = SHAP_{(Chem)} + SHAP_{(Storage)} + SHAP_{(WWTP)} + SHAP_{(Boilers)} + SHAP_{(Gen)}$$

Where:

$SHAP_{(Facility)}$ = Total tons of each SHAP emitted each month at Plant No. 34-01-015

$$SHAP_{(Chem)} = \sum [(Ef_{VOC} \times PP) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable CE})]$$

Where,

$SHAP_{(Chem)}$ = Total tons of each SHAP emitted from all chemical processes (including emissions from equipment leaks) at Plant No. 34-01-015

E_{fVOC} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP = Pounds of each product generated per process

Applicable CE = [(Percent efficiency of the control equipment listed in the construction permit for the emission point) / 100] (Zero for process steps with no control)

$SHAP_{(Storage)}$ = Total tons of each SHAP emitted from all storage tanks as determined using the most recent Chapter 7 of EPA's AP-42

$SHAP_{(WWTP)}$ = Total tons of SHAP emitted from the wastewater treatment plant as determined using the procedures in the permit.

$SHAP_{(Boilers)}$ = Total tons of SHAP emitted from the boilers as determined using the procedures in each applicable permit

$SHAP_{(Gen)}$ = Total tons of SHAP emitted from the non-emergency generators as determined using the procedures in each applicable permit.

- ii. The owner or operator shall record the total monthly amount, in tons, of each SHAP emitted from all the chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015. The owner or operator shall calculate the total monthly SHAP emissions using the equation in Construction Permit Condition 5b.J.i.
 - iii. The owner or operator shall calculate and record the total amount, in tons, of each SHAP emitted from all the chemical processes (including emissions from equipment leaks), storage tanks, wastewater treatment plant, boilers, and non-emergency generators at Plant No. 34-01-015 on a rolling 12-month basis.
- K. If the 12-month rolling total amount of SHAP emitted at Plant Number 34-01-015 exceeds 7.5 tons, the owner or operator shall immediately begin calculating daily SHAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015.
- i. The following requirements apply to the daily SHAP emissions calculations associated with the chemical processes (including emissions from equipment leaks) at Plant Number 34-01-015.
 - 1. The owner or operator may use the facility's emission inventory software (Emissions Accountant) to establish the daily emissions for the 12-month rolling period preceding the onset of daily emission recordkeeping.
 - a) The daily emission data for the previous 12 months (prior to onset) shall be an average of the monthly production data input to the facility's emissions accounting data system.
 - 2. The owner or operator shall maintain the following records:
 - a) The identification and quantity (pounds) of each product scheduled to be generated during each calendar year and the corresponding SHAP emissions, in tons.

- b) The projected total amount of SHAP emissions for each product, in tons.
 - c) The projected total amount of SHAP emissions for all products combined, in tons.
- 3. The projected emissions totals shall be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors shall be added once their respective batch record is finalized.
- 4. Projected emissions shall be totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The owner or operator shall enter the production data within 15 days of batch completion.
- ii. The following requirements apply to the daily SHAP emissions calculations from the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015.
 - 1. The owner or operator may assume the worst-case scenario for each source, i.e., the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators, based on data from the available 12-month period preceding the onset of daily emission recordkeeping.
 - a) The daily emission data for the previous 12 months (prior to onset) shall be the worst-case monthly emission values for each source averaged over the days in that month.
 - (1) The owner or operator shall determine the worst-case monthly emission values for the wastewater treatment plant, the boilers, and the non-emergency generators using the month with the highest combined emissions for each Single HAP.
 - (2) The owner or operator shall determine the worst-case monthly emission values for the storage tanks on a tank-by-tank basis.
 - 2. After each respective month is completed, the actual emissions will supersede the projected emissions. The actual daily emissions shall be calculated by averaging the actual emissions from that month for each source, using the procedures in each applicable permit, over the days in that month. The owner or operator shall enter the actual emissions data within 15 days of the end of the month.
- iii. The owner or operator shall record the total daily amount, in tons, of each SHAP emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015. The owner or operator shall calculate the total daily SHAP emissions using the equation in Construction Permit Condition 5b.J.i.
- iv. The owner may revise the daily SHAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators when monthly

- emissions are available
- v. Daily emission calculations and recordkeeping of SHAP emissions from the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall continue until the rolling 12-month total SHAP emissions from the facility drops below 7.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of SHAP emissions from these sources shall cease.

FACILITY-WIDE TOTAL HAP EMISSIONS LIMIT REQUIREMENTS

- L. The total amount of Total HAP (THAP) emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall not exceed 24.4 tons in any 12-month rolling period.
 - i. The owner or operator shall calculate the total amount, in tons, of THAP emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 using the following equation:

$$THAP_{(Facility)} = \sum (Total\ Emissions\ for\ each\ Single\ HAP)_{All\ Sources}$$

Where:
 $THAP_{(Facility)}$ = Total tons of Total HAP emitted at Plant No. 34-01-015
 - ii. The owner or operator shall record the total monthly amount, in tons, of THAP emitted from all the chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015. The owner or operator shall calculate the monthly THAP emissions using the equation in Construction Permit Condition 5b.L.i.
 - iii. The owner or operator shall calculate and record the amount, in tons, of THAP emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 on a rolling 12-month basis.
- M. If the 12-month rolling total amount of THAP emitted at Plant Number 34-01-015 exceeds 19.5 tons, the owner or operator shall immediately begin calculating daily THAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015.
 - i. The following requirements apply to the daily THAP emissions calculations associated with all chemical processes (including emissions from equipment leaks) at Plant No. 34-01-015.
 - 1. The owner or operator may use the facility's emission inventory software (Emissions Accountant) to establish the daily emissions for the 12-month rolling period preceding the onset of daily emission recordkeeping.

- a) The daily emission data for the previous 12 months (prior to onset) shall be an average of the monthly production data input to the facility's emissions accounting data system.
- 2. The owner or operator shall maintain the following records:
 - a) The identification and quantity (pounds) of each product scheduled to be generated during each calendar year and the corresponding THAP emissions, in tons.
 - b) The projected total amount of THAP emissions for each product, in tons.
 - c) The projected total amount of THAP emissions for all products combined, in tons.
- 3. The projected emissions totals shall be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors shall be added once their respective batch record is finalized.
- 4. Projected emissions shall be totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The owner or operator shall enter the actual production data within 15 days of batch completion.
- ii. The following requirements apply to the daily THAP emissions calculations from the storage tanks, wastewater treatment plant, boilers, and non-emergency generators at Plant No. 34-01-015.
 - 1. The owner or operator may assume the worst-case scenario for each source, i.e., the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators, based on data from the available 12-month period preceding the onset of daily emission recordkeeping.
 - a) The daily emission data for the previous 12 months (prior to onset) shall be the worst-case monthly emission values for each source averaged over the days in that month.
 - (1) The owner or operator shall determine the worst-case monthly emission values for the wastewater treatment plant, the boilers, and the non-emergency generators using the month with the highest combined THAP emissions.
 - (2) The owner or operator shall determine the worst-case monthly emission values for the storage tanks on a tank-by-tank basis.
 - 2. After each respective month is completed, the actual emissions will supersede the projected emissions. The actual daily emissions shall be calculated by averaging the actual emissions from that month for each source, using the procedures in each applicable permit, over the days in that month. The owner or operator shall enter the actual emissions data within 15 days of the end of the month.
- iii. The owner or operator shall record the total daily amount, in tons, of THAP emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-

emergency generators at Plant No. 34-01-015. The owner or operator shall calculate the daily THAP emissions using the equation in Construction Permit Condition 5b.L.i.

- iv. The owner may revise the daily THAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators when monthly emissions are available
- v. Daily emission calculations and recordkeeping of THAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall continue until the rolling 12-month THAP emissions from the facility drops below 19.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of THAP emissions from these sources shall cease.

VOC And HAP Emissions Reporting Requirements

- A. The owner or operator shall submit semi-annual reports on VOC and HAP emissions, in tons, from all operations.
 - (1) These reports shall contain the following information:
 - i. Facility-wide VOC emissions, in tons, for each month in the reporting period.
 - ii. Facility-wide emissions, in tons, of each Single HAP for each month in the reporting period.
 - iii. Facility-wide Total HAP emissions, in tons, for each month in the reporting period
 - (2) These reports shall be submitted by August 1 and February 1 of each year. The August report shall cover January through June and the February report shall cover July through December.
- B. The owner or operator shall submit deviation reports that identify all exceedances of the rolling 12-month emission limitations for VOC, Single HAP, and Total HAP.
 - (1) The owner or operator shall submit the report no later than 30 days from the end of the month in which the exceedance occurred.

Authority for Requirement: DNR Construction Permit 95-A-445-S22

Emission Point Characteristics

The emission point shall conform to the specifications listed below.

Stack Height, (ft, from the ground): 58

Stack Opening, (inches, dia.): 18

Exhaust Flow Rate (scfm): 4,000

Exhaust Temperature (°F): 160

Discharge Style: Vertical Unobstructed

Authority for Requirement: DNR Construction Permit 95-A-445-S22

The temperature and flowrate are intended to be representative and characteristic of the design of the permitted emission point. The Department recognizes that the temperature and flow rate may vary with changes in the process and ambient conditions. If it is determined that either the temperature or flowrate above are different than the values stated, the owner or operator shall

submit a request to the Department within thirty (30) days of the discovery to determine if a permit amendment is required or submit a permit application requesting to amend the permit.

Monitoring Requirements

The owner/operator of this equipment shall comply with the monitoring requirements listed below.

Agency Approved Operation & Maintenance Plan Required? Yes ☐ No ☒

Facility Maintained Operation & Maintenance Plan Required? Yes ☐ No ☒

Compliance Assurance Monitoring (CAM) Plan Required? Yes ☐ No ☒

Authority for Requirement: 567 IAC 22.108(3)

Emission Point ID Number: EP 304

Associated Equipment

Emission Unit	Emission Unit Description	Raw Material	Reactor Capacity	Construction Permit
R-3142	Reactor (Bypass)	Pharmaceutical Raw Materials	2,000 gallons	12-A-561-S2
R-3144	Reactor (Bypass)	Pharmaceutical Raw Materials	2,000 gallons	

Applicable Requirements

Emission Limits (lb./hr, gr./dscf, lb./MMBtu, % opacity, etc.)

The emissions from this emission point shall not exceed the levels specified below.

See "Plant-Wide Conditions" for applicable emission limits.

NESHAP Applicability

This facility is of the source type regulated under the National Emission Standard for Hazardous Air Pollutants (NESHAP) for Chemical Manufacturing Area Sources (40 CFR 63 Subpart VVVVVV) and 40 CFR 63 Subpart A – General Provisions.

Authority for Requirement: 40 CFR 63 Subpart A
567 IAC 23.1(4)
40 CFR 63 Subpart VVVVVV
567 IAC 23.1(4)"ev"
DNR Construction Permit 12-A-561-S2

Operating Requirements with Associated Monitoring and Recordkeeping

All records as required by this permit shall be kept on-site for a minimum of five (5) years and shall be available for inspection by the Department. Records shall be legible and maintained in an orderly manner. The operating requirements and associated recordkeeping for this permit shall be:

GENERAL REQUIREMENTS

- A. The equipment used to make each product (i.e. chemical process) may exhaust through several emission points (controlled or uncontrolled). The permittee shall maintain records on the identification of each process and the identification of the process's emission points.
- B. The permittee shall maintain the following records for each batch run in the equipment covered by this permit:
 - i. The identification and amount (gallons or pounds) of all materials used in the development of the emission factors for the purpose of determining the emission rates from the equipment covered by this permit.
 - ii. The identification and quantity of each final product generated.
- C. The owner or operator shall develop and document uncontrolled VOC emission factors

(E_{fVOC}), in pounds of VOC per pound of product and uncontrolled Single HAP emission factors (E_{fSHAP}), in pounds of Single HAP per pound of product, to determine VOC and HAP emissions from the production of each final product using the equipment listed in Construction Permit Condition 3b.

- i. The calculation of each emission factor shall be subject to the review and approval of the Department. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, during the production of a specific product to confirm the accuracy of the emission factor.
- D. The owner or operator shall determine uncontrolled VOC and HAP emission rates by using one of the following methods:
 - (a) For pharmaceutical products, for emissions from vapor displacement, purging, heating, depressurization, gas evolution, air drying, and empty vessel purging, the appropriate equations from §63.1257(d)(2)(i) (40 CFR Part 63, Subpart GGG) shall be used.
 - (b) For other emission episodes in the production of pharmaceutical products, appropriate estimation methods as stated in § 63.1257(d)(2)(ii) (40 CFR Part 63, Subpart GGG) shall be used.
 - (c) For non-pharmaceutical products, appropriate resources, including “Methods for Estimating Air Emissions from Chemical Manufacturing Facilities” and the “pharmaceutical MACT” shall be used.
 - (d) For non-pharmaceutical products where no U.S. EPA emission calculations are applicable, standard engineering principles shall be used to best represent the emission rate from the unit.
 - (e) For breathing and working losses from storage tanks, the appropriate equations and methods provided in EPA’s most recent AP-42 (Compilation of Air Pollutant Emission Factors) shall be used.
- E. The permittee shall maintain the following monthly records:
 - i. The controlled vent emission rate of each HAP and VOC for each batch of chemicals processed in the equipment covered by this permit. The controlled vent emission rates shall be determined by using one of the following methods:
 - (a) For water soluble organic HAPs or VOC, multiply the uncontrolled emission rate by $(1 - 0.95)$, where 0.95 represents the control efficiency of the scrubber. This control efficiency is based on the manufacturer’s design specifications and performance data. If necessary, the permittee shall conduct emission testing, at the request of the Iowa DNR - Air Quality Bureau, to verify the estimate of the scrubber’s control efficiency.
 - (b) For inorganic acidic HAP emissions, multiply the uncontrolled emission rate by $(1 - 0.98)$, where 0.98 represents the control efficiency of the scrubber. This control efficiency is based on the manufacturer’s design specifications and performance data. If necessary, the permittee shall conduct emission testing, at the request of the Iowa DNR - Air Quality Bureau, to verify the estimate of the scrubber’s control efficiency.
 - (c) For other HAPs and VOCs, the solubility of the pollutant in the respective scrubber media shall be used to determine the scrubber’s removal efficiency. The uncontrolled emissions rate should be multiplied by $(1 - x)$, where x is the control efficiency of the scrubber for the air contaminant as determined by its solubility in

the scrubber media. This takes into consideration the reduced control efficiency due to insolubility of certain air contaminants in the scrubbing media.

- (d) For VOC and HAP emissions controlled by the carbon adsorption unit, multiply the uncontrolled emission rate by $(1 - 0.95)$, where 0.95 represents the control efficiency of the vapor phase carbon adsorption unit. This control efficiency is based on the manufacturer's design specifications and performance data. If necessary, the permittee shall conduct emission testing, at the request of the Iowa DNR - Air Quality Bureau, to verify the estimate of the scrubber's control efficiency.
 - (e) For VOC and HAP emissions controlled by the Cryogenic Vapor Recovery Unit, multiply the uncontrolled emission rate by $(1 - 0.98)$, where 0.98 represents the control efficiency of the Cryogenic Vapor Recovery Unit. This control efficiency is based on the manufacturer's design specifications and performance data. If necessary, the permittee shall conduct emission testing, at the request of the Iowa DNR - Air Quality Bureau, to verify the estimate of the Cryogenic Vapor Recovery Unit's control efficiency.
- F. The owner or operator shall use and update, as needed, the procedures developed to calculate VOC, Single HAP, and Total HAP daily emissions. These procedures shall be implemented if and when the 12-month rolling total for VOC, Single HAP, and Total HAP reaches 78.4 tons, 7.5 tons, and 19.5 tons, respectively (see Construction Permit Conditions 5.L, 5.N, and 5.P).
- iii. At a minimum, the procedures shall include the following:
 - i. Methodology to be followed and an explanation of how the selected methodology will reliably determine daily emissions.
 - ii. Description of the time needed to compile the information needed to complete the daily emissions calculations.
 - iii. Description of the records needed to perform daily emissions calculations.

VOC EMISSIONS CALCULATIONS REQUIREMENTS for EQUIPMENT in this EMISSION POINT

- E. The owner shall calculate monthly VOC emissions, in tons, using the following equation:

Monthly VOC Emissions:

$$\text{VOC}_{\text{Month(c)}} = \sum[(\text{Ef}_{\text{VOC}} \times \text{PP}_{\text{Month}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{VOC}_{\text{Month(c)}}$ = Total tons of VOC emitted each month

Ef_{VOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP_{Month} = Pounds of each product generated per process each month

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- F. The owner or operator shall record the total monthly ($\text{VOC}_{\text{Month(c)}}$) VOC emissions, in tons, from the production of each product using the equipment listed in Construction Permit Condition 3b.

SINGLE HAP EMISSIONS CALCULATIONS REQUIREMENTS for EQUIPMENT in this EMISSION POINT

- G. The owner or operator shall calculate monthly emissions, in tons, for each Single HAP using the following equations:

Monthly Single HAP Emissions:

$$SHAP_{\text{Month}(c)} = \sum [(E_{f\text{SHAP}} \times PP_{\text{Month}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$SHAP_{\text{Month}(c)}$ = Total tons of Single HAP (SHAP) emitted each month

$E_{f\text{SHAP}}$ = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Month} = Pounds of each product generated per process each month

Applicable Control Efficiency = [(Percent efficiency of the control equipment as

specified in the construction permit for the emission point) / 100]

(Zero for process steps with no control)

- H. The owner or operator shall record the monthly ($SHAP_{\text{Month}(c)}$) emissions, in tons, for each Single HAP (SHAP) from the production of each product using the equipment listed in Construction Permit Condition 3b.

TOTAL HAP EMISSIONS CALCULATIONS REQUIREMENTS for EQUIPMENT in this EMISSION POINT

- I. The owner or operator shall calculate monthly Total HAP emissions, in tons, using the following equations:

- i. Monthly Total HAP Emissions:

$$THAP_{\text{Month}(c)} = \sum (\text{Monthly Emissions} \left(\frac{\text{tons}}{\text{month}} \right) \text{ for each Single HAP})$$

Where:

$THAP_{\text{Month}(c)}$ = Total tons of Total HAP emitted each month

- J. The owner or operator shall record the total monthly ($THAP_{\text{Month}(c)}$) Total HAP emissions, in tons, from the production of each product using the equipment listed in Construction Permit Condition 3b by using Single HAP emissions as indicated in Construction Permit Condition 5.G.

FACILITY-WIDE VOC EMISSIONS LIMIT REQUIREMENTS

- K. The total amount of VOC emitted, facility-wide, at Plant Number 34-01-015 shall not exceed 98 tons in any 12-month rolling period.

(1) The owner or operator shall record the total amount, in tons, of VOC emitted from all sources (e.g., chemical processes, combustion, tanks, wastewater, etc.) at Plant Number 34-01-015 on a monthly basis.

(2) The owner or operator shall calculate and record the total amount, in tons, of VOC emitted from all sources at Plant Number 34-01-015 on a rolling 12-month basis.

- L. If the 12-month rolling total amount of VOC emitted at the facility (Plant Number 34-01-015) exceeds 78.4 tons, the permittee shall immediately begin calculating the daily emissions from the chemical processes. The following records and procedures shall be used:

(1) The identification and quantity (pounds) of each product scheduled to be generated during each calendar day and the corresponding VOC emissions, in tons.

- (2) The projected total amount of VOC emissions for each product, in tons.
- (3) The projected total amount of VOC emissions for all products combined, in tons.
- (4) The 365-day rolling total amount of VOC emissions for all products produced in the chemical processes, in tons.
- (5) The facility is not required to retroactively determine daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The facility may use its emissions accounting software (i.e., data system) to establish the daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The daily data from the previous 12-months (prior to onset) will be an average of the monthly production data input to the facility's emissions accounting data system.
- (6) The projected emission totals will be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors will be added once their respective batch record is finalized.
- (7) Projected emissions are totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The actual production data will be entered within 15 days of batch completion.
- (8) The owner or operator shall calculate daily VOC emissions from the chemical processes at Plant Number 34-01-015 using the following equation:

$$\text{VOC}_{\text{Day(c)}} = \sum[(\text{Ef}_{\text{VOC}} \times \text{PP}_{\text{Day}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{VOC}_{\text{Day(c)}}$ = Total tons of VOC emitted each day from the chemical processes

Ef_{VOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP_{Day} = Pounds of each product generated per process each day

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- (9) Daily emission calculations and recordkeeping of VOC emissions from the chemical processes at Plant Number 34-01-015 shall continue until the rolling 12-month total VOC emissions from the facility drops below 78.4 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of VOC emissions from the chemical processes shall cease.

FACILITY-WIDE SINGLE HAP EMISSIONS LIMIT REQUIREMENTS

M. The total amount for each Single HAP (SHAP) emitted at Plant Number 34-01-015 shall not exceed 9.4 tons in any 12-month rolling period.

- (1) The owner or operator shall record the total amount, in tons, of each Single HAP (SHAP) emitted from all sources (e.g., chemical processes, combustion, tanks, wastewater, etc.) at Plant Number 34-01-015 on a monthly basis.
- (2) The owner or operator shall calculate and record the total amount, in tons, of each Single HAP (SHAP) emitted from all sources at Plant Number 34-01-015 on a rolling 12-month basis.

N. If the 12-month rolling total amount of any SHAP emitted at the facility (Plant Number 34-01-015) exceeds 7.5 tons, the permittee shall immediately begin calculating the daily emissions

from the chemical processes. The following records and procedures shall be used:

- (1) The identification and quantity (pounds) of each product scheduled to be generated during each calendar day and the corresponding SHAP emissions, in tons.
- (2) The projected total amount of SHAP emissions for each product, in tons.
- (3) The projected total amount of SHAP emissions for all products combined, in tons.
- (4) The 365-day rolling total amount of SHAP emissions for all products produced in the chemical processes, in tons.
- (5) The facility is not required to retroactively determine daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The facility may use its emissions accounting software (i.e., data system) to establish the daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The daily data from the previous 12-months (prior to onset) will be an average of the monthly production data input to the facility's emissions accounting data system.
- (6) The projected emission totals will be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors will be added once their respective batch record is finalized.
- (7) Projected emissions are totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The actual production data will be entered within 15 days of batch completion.
- (8) The owner or operator shall calculate daily SHAP emissions from the chemical processes at Plant Number 34-01-015 using the following equation:

$$\text{SHAP}_{\text{Day(c)}} = \sum[(\text{Ef}_{\text{SHAP}} \times \text{PP}_{\text{Day}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{SHAP}_{\text{Day(c)}}$ = Total tons of SHAP emitted each day from the chemical processes

Ef_{SHAPC} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Day} = Pounds of each product generated per process each day

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- (9) Daily emission calculations and recordkeeping of SHAP emissions from the chemical processes at Plant Number 34-01-015 shall continue until the rolling 12-month total SHAP emissions from the facility drops below 7.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of SHAP emissions from the chemical processes shall cease.

FACILITY-WIDE TOTAL HAP EMISSIONS LIMIT REQUIREMENTS

- O. The total amount of Total HAPs (THAPs) emitted at Plant Number 34-01-015 shall not exceed 24.4 tons in any 12-month rolling period.
 - (1) The owner or operator shall record the total amount, in tons, of Total HAP (THAP) emitted from all sources (e.g., chemical processes, combustion, tanks, wastewater, etc.) at Plant Number 34-01-015 on a monthly basis.
 - (2) The owner or operator shall calculate and record the total amount, in tons, of Total HAP (THAP) emitted from all sources at Plant Number 34-01-015 on a rolling 12-

month basis.

P. If the 12-month rolling total amount of THAP emitted at the facility (Plant Number 34-01-015) exceeds 19.5 tons, the permittee shall immediately begin calculating the daily emissions from the chemical processes. The following records and procedures shall be used:

- (1) The identification and quantity (pounds) of each product scheduled to be generated during each calendar day and the corresponding THAP emissions, in tons.
- (2) The projected total amount of THAP emissions for each product, in tons.
- (3) The projected total amount of THAP emissions for all products combined, in tons.
- (4) The 365-day rolling total amount of THAP emissions for all products produced in the chemical processes, in tons.
- (5) The facility is not required to retroactively determine daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The facility may use its emissions accounting software (i.e., data system) to establish the daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The daily data from the previous 12-months (prior to onset) will be an average of the monthly production data input to the facility's emissions accounting data system.
- (6) The projected emission totals will be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors will be added once their respective batch record is finalized.
- (7) Projected emissions are totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The actual production data will be entered within 15 days of batch completion.
- (8) The owner or operator shall calculate daily SHAP emissions from the chemical processes at Plant Number 34-01-015 using the following equation:

$$\text{THAP}_{\text{Day(c)}} = \sum[(\text{Ef}_{\text{THAP}} \times \text{PP}_{\text{Day}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{THAP}_{\text{Day(c)}}$ = Total tons of SHAP emitted each day from the chemical processes

Ef_{THAPC} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Day} = Pounds of each product generated per process each day

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- (9) Daily emission calculations and recordkeeping of THAP emissions from the chemical processes at Plant Number 34-01-015 shall continue until the rolling 12-month total THAP emissions from the facility drops below 19.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of SHAP emissions from the chemical processes shall cease.

VOC and HAP EMISSIONS REPORTING REQUIREMENTS

Q. The owner or operator shall submit semi-annual reports on VOC and HAP emissions, in tons, from all operations at Plant Number 34-01-015.

(1) These reports shall contain the following information:

- i. Facility-wide VOC emissions, in tons, for each month in the reporting period.
- ii. Facility-wide emissions, in tons, of each Single HAP for each month in the reporting period.
- iii. Facility-wide Total HAP emissions, in tons, for each month in the reporting period

(2) These reports shall be submitted by August 1 and February 1 of each year. The August report shall cover January through June and the February report shall cover July through December.

R. The owner or operator shall submit deviation reports that identify all exceedances of the rolling 12-month emission limitations for VOC, Single HAP, and Total HAP.

(1) The owner or operator shall submit the report no later than 30 days from the end of the month in which the exceedance occurred.

Authority for Requirement: DNR Construction Permit 12-A-561-S2

Emission Point Characteristics

The emission point shall conform to the specifications listed below.

Stack Height, (ft, from the ground): 30

Stack Opening, (inches, dia.): 2

Exhaust Flow Rate (scfm): 0 – 1,800

Exhaust Temperature (°F): 0 - 160

Discharge Style: Vertical obstructed

Authority for Requirement: Iowa DNR Construction Permit 12-A-561-S2

The temperature and flowrate are intended to be representative and characteristic of the design of the permitted emission point. The Department recognizes that the temperature and flow rate may vary with changes in the process and ambient conditions. If it is determined that either the temperature or flowrate above are different than the values stated, the owner or operator shall submit a request to the Department within thirty (30) days of the discovery to determine if a permit amendment is required or submit a permit application requesting to amend the permit.

Monitoring Requirements

The owner/operator of this equipment shall comply with the monitoring requirements listed below.

Agency Approved Operation & Maintenance Plan Required? Yes ☐ No ☒

Facility Maintained Operation & Maintenance Plan Required? Yes ☐ No ☒

Compliance Assurance Monitoring (CAM) Plan Required? Yes ☐ No ☒

Authority for Requirement: 567 IAC 22.108(3)

Emission Point ID Number: EP 306

Associated Equipment

Emission Unit	Emission Unit Description	Raw Material	Reactor Capacity	Construction Permit
R-3150	Reactor Tanks (Bypass)	Pharmaceutical Raw Materials	4,000 gallons	13-A-176-S2

Applicable Requirements

Emission Limits (lb./hr, gr./dscf, lb./MMBtu, % opacity, etc.)

The emissions from this emission point shall not exceed the levels specified below.

See "Plant-Wide Conditions" for applicable emission limits.

NESHAP Applicability

This facility is of the source type regulated under the National Emission Standard for Hazardous Air Pollutants (NESHAP) for Chemical Manufacturing Area Sources (40 CFR 63 Subpart VVVVVV) and 40 CFR 63 Subpart A – General Provisions.

Authority for Requirement: 40 CFR 63 Subpart A
567 IAC 23.1(4)
40 CFR 63 Subpart VVVVVV
567 IAC 23.1(4)"ev"
DNR Construction Permit 13-A-176-S2

Operating Requirements with Associated Monitoring and Recordkeeping

All records as required by this permit shall be kept on-site for a minimum of five (5) years and shall be available for inspection by the Department. Records shall be legible and maintained in an orderly manner. The operating requirements and associated recordkeeping for this permit shall be:

GENERAL REQUIREMENTS

- A. The equipment used to make each product (i.e. chemical process) may exhaust through several emission points (controlled or uncontrolled). The permittee shall maintain records on the identification of each process and the identification of the process's emission points.
- B. The permittee shall maintain the following records for each batch run in the equipment covered by this permit:
 - iii. The identification and amount (gallons or pounds) of all materials used in the development of the emission factors for the purpose of determining the emission rates from the equipment covered by this permit.
 - iv. The identification and quantity of each final product generated.
- C. The owner or operator shall develop and document uncontrolled VOC emission factors (E_{fVOC}), in pounds of VOC per pound of product and uncontrolled Single HAP emission factors (E_{fSHAP}), in pounds of Single HAP per pound of product, to determine VOC and HAP emissions from the production of each final product using the equipment listed in

Construction Permit Condition 3b.

- i. The calculation of each emission factor shall be subject to the review and approval of the Department. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, during the production of a specific product to confirm the accuracy of the emission factor.
- D. The owner or operator shall determine uncontrolled VOC and HAP emission rates by using one of the following methods:
 - (a) For pharmaceutical products, for emissions from vapor displacement, purging, heating, depressurization, gas evolution, air drying, and empty vessel purging, the appropriate equations from §63.1257(d)(2)(i) (40 CFR Part 63, Subpart GGG) shall be used.
 - (b) For other emission episodes in the production of pharmaceutical products, appropriate estimation methods as stated in § 63.1257(d)(2)(ii) (40 CFR Part 63, Subpart GGG) shall be used.
 - (c) For non-pharmaceutical products, appropriate resources, including “Methods for Estimating Air Emissions from Chemical Manufacturing Facilities” and the “pharmaceutical MACT” shall be used.
 - (d) For non-pharmaceutical products where no U.S. EPA emission calculations are applicable, standard engineering principles shall be used to best represent the emission rate from the unit.
 - (e) For breathing and working losses from storage tanks, the appropriate equations and methods provided in EPA’s most recent AP-42 (Compilation of Air Pollutant Emission Factors) shall be used.
- E. The permittee shall maintain the following monthly records:
 - ii. The controlled vent emission rate of each HAP and VOC for each batch of chemicals processed in the equipment covered by this permit. The controlled vent emission rates shall be determined by using one of the following methods:
 - (f) For water soluble organic HAPs or VOC, multiply the uncontrolled emission rate by $(1 - 0.95)$, where 0.95 represents the control efficiency of the scrubber. This control efficiency is based on the manufacturer’s design specifications and performance data. If necessary, the permittee shall conduct emission testing, at the request of the Iowa DNR - Air Quality Bureau, to verify the estimate of the scrubber’s control efficiency.
 - (g) For inorganic acidic HAP emissions, multiply the uncontrolled emission rate by $(1 - 0.98)$, where 0.98 represents the control efficiency of the scrubber. This control efficiency is based on the manufacturer’s design specifications and performance data. If necessary, the permittee shall conduct emission testing, at the request of the Iowa DNR - Air Quality Bureau, to verify the estimate of the scrubber’s control efficiency.
 - (h) For other HAPs and VOCs, the solubility of the pollutant in the respective scrubber media shall be used to determine the scrubber’s removal efficiency. The uncontrolled emissions rate should be multiplied by $(1 - x)$, where x is the control efficiency of the scrubber for the air contaminant as determined by its solubility in the scrubber media. This takes into consideration the reduced control efficiency due to insolubility of certain air contaminants in the scrubbing media.

- (i) For VOC and HAP emissions controlled by the carbon adsorption unit, multiply the uncontrolled emission rate by $(1 - 0.95)$, where 0.95 represents the control efficiency of the vapor phase carbon adsorption unit. This control efficiency is based on the manufacturer's design specifications and performance data. If necessary, the permittee shall conduct emission testing, at the request of the Iowa DNR - Air Quality Bureau, to verify the estimate of the scrubber's control efficiency.
 - (j) For VOC and HAP emissions controlled by condensers H-3110A and/or H-3110B, multiply the uncontrolled emission rate by $(1 - 0.95)$, where 0.95 represents the control efficiency of the condensers. This control efficiency is based on the manufacturer's design specifications and performance data. If necessary, the permittee shall conduct emission testing, at the request of the Iowa DNR - Air Quality Bureau, to verify the estimate of the condensers' control efficiency.
- F. The owner or operator shall use and update, as needed, the procedures developed to calculate VOC, Single HAP, and Total HAP daily emissions. These procedures shall be implemented if and when the 12-month rolling total for VOC, Single HAP, and Total HAP reaches 78.4 tons, 7.5 tons, and 19.5 tons, respectively (see Construction Permit Conditions 5.N, 5.P, and 5.R).
- iv. At a minimum, the procedures shall include the following:
 - i. Methodology to be followed and an explanation of how the selected methodology will reliably determine daily emissions.
 - ii. Description of the time needed to compile the information needed to complete the daily emissions calculations.
 - iii. Description of the records needed to perform daily emissions calculations.

VOC EMISSIONS CALCULATIONS REQUIREMENTS for EQUIPMENT in this EMISSION POINT

- G. The owner shall calculate monthly VOC emissions, in tons, using the following equation:

Monthly VOC Emissions:

$$\text{VOC}_{\text{Month(c)}} = \sum[(\text{Ef}_{\text{VOC}} \times \text{PP}_{\text{Month}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{VOC}_{\text{Month(c)}}$ = Total tons of VOC emitted each month

Ef_{VOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP_{Month} = Pounds of each product generated per process each month

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- H. The owner or operator shall record the total monthly ($\text{VOC}_{\text{Month(c)}}$) VOC emissions, in tons, from the production of each product using the equipment listed in Construction Permit Condition 3b.

SINGLE HAP EMISSIONS CALCULATIONS REQUIREMENTS for EQUIPMENT in this EMISSION POINT

- I. The owner or operator shall calculate monthly emissions, in tons, for each Single HAP using the following equations:

Monthly Single HAP Emissions:

$$SHAP_{Month(c)} = \sum [(Ef_{SHAP} \times PP_{Month}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$SHAP_{Month(c)}$ = Total tons of Single HAP (SHAP) emitted each month

Ef_{SHAP} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Month} = Pounds of each product generated per process each month

Applicable Control Efficiency = [(Percent efficiency of the control equipment as

specified in the construction permit for the emission point) / 100]

(Zero for process steps with no control)

- J. The owner or operator shall record the monthly ($SHAP_{Month(c)}$) emissions, in tons, for each Single HAP (SHAP) from the production of each product using the equipment listed in Construction Permit Condition 3b.

TOTAL HAP EMISSIONS CALCULATIONS REQUIREMENTS for EQUIPMENT in this EMISSION POINT

- K. The owner or operator shall calculate monthly Total HAP emissions, in tons, using the following equations:

- ii. Monthly Total HAP Emissions:

$$THAP_{Month(c)} = \sum (Monthly \text{ Emissions} \left(\frac{tons}{month} \right) \text{ for each Single HAP})$$

Where:

$THAP_{Month(c)}$ = Total tons of Total HAP emitted each month

- L. The owner or operator shall record the total monthly ($THAP_{Month(c)}$) Total HAP emissions, in tons, from the production of each product using the equipment listed in Construction Permit Condition 3b by using Single HAP emissions as indicated in Construction Permit Condition 5.I.

FACILITY-WIDE VOC EMISSIONS LIMIT REQUIREMENTS

- M. The total amount of VOC emitted, facility-wide, at Plant Number 34-01-015 shall not exceed 98 tons in any 12-month rolling period.

(1) The owner or operator shall record the total amount, in tons, of VOC emitted from all sources (e.g., chemical processes, combustion, tanks, wastewater, etc.) at Plant Number 34-01-015 on a monthly basis.

(2) The owner or operator shall calculate and record the total amount, in tons, of VOC emitted from all sources at Plant Number 34-01-015 on a rolling 12-month basis.

- N. If the 12-month rolling total amount of VOC emitted at the facility (Plant Number 34-01-015) exceeds 78.4 tons, the permittee shall immediately begin calculating the daily emissions from the chemical processes. The following records and procedures shall be used:

- (1) The identification and quantity (pounds) of each product scheduled to be generated during each calendar day and the corresponding VOC emissions, in tons.
- (2) The projected total amount of VOC emissions for each product, in tons.
- (3) The projected total amount of VOC emissions for all products combined, in tons.
- (4) The 365-day rolling total amount of VOC emissions for all products produced in the chemical processes, in tons.
- (5) The facility is not required to retroactively determine daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The facility may use its emissions accounting software (i.e., data system) to establish the daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The daily data from the previous 12-months (prior to onset) will be an average of the monthly production data input to the facility's emissions accounting data system.
- (6) The projected emission totals will be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors will be added once their respective batch record is finalized.
- (7) Projected emissions are totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The actual production data will be entered within 15 days of batch completion.
- (8) The owner or operator shall calculate daily VOC emissions from the chemical processes at Plant Number 34-01-015 using the following equation:

$$\text{VOC}_{\text{Day(c)}} = \sum[(\text{Ef}_{\text{VOC}} \times \text{PP}_{\text{Day}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{VOC}_{\text{Day(c)}}$ = Total tons of VOC emitted each day from the chemical processes

Ef_{VOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP_{Day} = Pounds of each product generated per process each day

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- (9) Daily emission calculations and recordkeeping of VOC emissions from the chemical processes at Plant Number 34-01-015 shall continue until the rolling 12-month total VOC emissions from the facility drops below 78.4 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of VOC emissions from the chemical processes shall cease.

FACILITY-WIDE SINGLE HAP EMISSIONS LIMIT REQUIREMENTS

O. The total amount for each Single HAP (SHAP) emitted at Plant Number 34-01-015 shall not exceed 9.4 tons in any 12-month rolling period.

- (1) The owner or operator shall record the total amount, in tons, of each Single HAP (SHAP) emitted from all sources (e.g., chemical processes, combustion, tanks, wastewater, etc.) at Plant Number 34-01-015 on a monthly basis.
- (2) The owner or operator shall calculate and record the total amount, in tons, of each Single HAP (SHAP) emitted from all sources at Plant Number 34-01-015 on a rolling 12-month basis.

P. If the 12-month rolling total amount of any SHAP emitted at the facility (Plant Number 34-01-015) exceeds 7.5 tons, the permittee shall immediately begin calculating the daily emissions from the chemical processes. The following records and procedures shall be used:

- (1) The identification and quantity (pounds) of each product scheduled to be generated during each calendar day and the corresponding SHAP emissions, in tons.
- (2) The projected total amount of SHAP emissions for each product, in tons.
- (3) The projected total amount of SHAP emissions for all products combined, in tons.
- (4) The 365-day rolling total amount of SHAP emissions for all products produced in the chemical processes, in tons.
- (5) The facility is not required to retroactively determine daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The facility may use its emissions accounting software (i.e., data system) to establish the daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The daily data from the previous 12-months (prior to onset) will be an average of the monthly production data input to the facility's emissions accounting data system.
- (6) The projected emission totals will be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors will be added once their respective batch record is finalized.
- (7) Projected emissions are totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The actual production data will be entered within 15 days of batch completion.
- (8) The owner or operator shall calculate daily SHAP emissions from the chemical processes at Plant Number 34-01-015 using the following equation:

$$\text{SHAP}_{\text{Day}(c)} = \sum[(\text{Ef}_{\text{SHAP}} \times \text{PP}_{\text{Day}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{SHAP}_{\text{Day}(c)}$ = Total tons of SHAP emitted each day from the chemical processes

Ef_{SHAPC} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Day} = Pounds of each product generated per process each day

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- (9) Daily emission calculations and recordkeeping of SHAP emissions from the chemical processes at Plant Number 34-01-015 shall continue until the rolling 12-month total SHAP emissions from the facility drops below 7.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of SHAP emissions from the chemical processes shall cease.

FACILITY-WIDE TOTAL HAP EMISSIONS LIMIT REQUIREMENTS

Q. The total amount of Total HAPs (THAPs) emitted at Plant Number 34-01-015 shall not exceed 24.4 tons in any 12-month rolling period.

- (1) The owner or operator shall record the total amount, in tons, of Total HAP (THAP) emitted from all sources (e.g., chemical processes, combustion, tanks, wastewater, etc.) at Plant Number 34-01-015 on a monthly basis.

- (2) The owner or operator shall calculate and record the total amount, in tons, of Total HAP (THAP) emitted from all sources at Plant Number 34-01-015 on a rolling 12-month basis.
- R. If the 12-month rolling total amount of THAP emitted at the facility (Plant Number 34-01-015) exceeds 19.5 tons, the permittee shall immediately begin calculating the daily emissions from the chemical processes. The following records and procedures shall be used:
- (1) The identification and quantity (pounds) of each product scheduled to be generated during each calendar day and the corresponding THAP emissions, in tons.
 - (2) The projected total amount of THAP emissions for each product, in tons.
 - (3) The projected total amount of THAP emissions for all products combined, in tons.
 - (4) The 365-day rolling total amount of THAP emissions for all products produced in the chemical processes, in tons.
 - (5) The facility is not required to retroactively determine daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The facility may use its emissions accounting software (i.e., data system) to establish the daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The daily data from the previous 12-months (prior to onset) will be an average of the monthly production data input to the facility's emissions accounting data system.
 - (6) The projected emission totals will be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors will be added once their respective batch record is finalized.
 - (7) Projected emissions are totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The actual production data will be entered within 15 days of batch completion.
 - (8) The owner or operator shall calculate daily SHAP emissions from the chemical processes at Plant Number 34-01-015 using the following equation:

$$THAP_{Day(c)} = \sum [(Ef_{THAP} \times PP_{Day}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

 - $THAP_{Day(c)}$ = Total tons of SHAP emitted each day from the chemical processes
 - Ef_{THAP} = Process-specific emission factor for SHAP (lb SHAP / lb product)
 - PP_{Day} = Pounds of each product generated per process each day
 - Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)
 - (9) Daily emission calculations and recordkeeping of THAP emissions from the chemical processes at Plant Number 34-01-015 shall continue until the rolling 12-month total THAP emissions from the facility drops below 19.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of SHAP emissions from the chemical processes shall cease.

VOC and HAP EMISSIONS REPORTING REQUIREMENTS

- S. The owner or operator shall submit semi-annual reports on VOC and HAP emissions, in tons, from all operations at Plant Number 34-01-015.
- (1) These reports shall contain the following information:
 - i. Facility-wide VOC emissions, in tons, for each month in the reporting period.
 - ii. Facility-wide emissions, in tons, of each Single HAP for each month in the reporting period.
 - iii. Facility-wide Total HAP emissions, in tons, for each month in the reporting period
 - (2) These reports shall be submitted by August 1 and February 1 of each year. The August report shall cover January through June and the February report shall cover July through December.
- T. The owner or operator shall submit deviation reports that identify all exceedances of the rolling 12-month emission limitations for VOC, Single HAP, and Total HAP.
- a. The owner or operator shall submit the report no later than 30 days from the end of the month in which the exceedance occurred.

Authority for Requirement: DNR Construction Permit 13-A-176-S2

Emission Point Characteristics

The emission point shall conform to the specifications listed below.

Stack Height, (ft, from the ground): 54

Stack Opening, (inches, dia.): 2

Exhaust Flow Rate (scfm): 0 -100

Exhaust Temperature (°F): 0 - 95

Discharge Style: Vertical obstructed

Authority for Requirement: DNR Construction Permit 13-A-176-S2

The temperature and flowrate are intended to be representative and characteristic of the design of the permitted emission point. The Department recognizes that the temperature and flow rate may vary with changes in the process and ambient conditions. If it is determined that either the temperature or flowrate above are different than the values stated, the owner or operator shall submit a request to the Department within thirty (30) days of the discovery to determine if a permit amendment is required or submit a permit application requesting to amend the permit.

Monitoring Requirements

The owner/operator of this equipment shall comply with the monitoring requirements listed below.

Agency Approved Operation & Maintenance Plan Required? Yes ☐ No ☒

Facility Maintained Operation & Maintenance Plan Required? Yes ☐ No ☒

Compliance Assurance Monitoring (CAM) Plan Required? Yes ☐ No ☒

Authority for Requirement: 567 IAC 22.108(3)

Emission Point ID Number: EP 308

Associated Equipment

Emission Unit	Emission Unit Description	Raw Material	Rated Capacity	Construction Permit
R-3160	Reactor (Bypass for Hydrogen)	Pharmaceutical Raw Materials	2,500 gallons	14-A-626-S2
R-3186	Reactor (Bypass for Hydrogen)	Pharmaceutical Raw Materials	1,000 gallons	

Applicable Requirements

Emission Limits (lb./hr, gr./dscf, lb./MMBtu, % opacity, etc.)

The emissions from this emission point shall not exceed the levels specified below.

See "Plant-Wide Conditions" for applicable emission limits.

NESHAP Applicability

This facility is of the source type regulated under the National Emission Standard for Hazardous Air Pollutants (NESHAP) for Chemical Manufacturing Area Sources (40 CFR 63 Subpart VVVVVV) and 40 CFR 63 Subpart A – General Provisions.

Authority for Requirement: 40 CFR 63 Subpart A
567 IAC 23.1(4)
40 CFR 63 Subpart VVVVVV
567 IAC 23.1(4)"ev"
DNR Construction Permit 14-A-626-S2

Operating Requirements with Associated Monitoring and Recordkeeping

All records as required by this permit shall be kept on-site for a minimum of five (5) years and shall be available for inspection by the Department. Records shall be legible and maintained in an orderly manner. The operating requirements and associated recordkeeping for this permit shall be:

- A. The process equipment (reactors) covered by this permit may exhaust through several permitted emission points (controlled or uncontrolled).
 - (1) The owner or operator shall maintain records on the identification of the equipment and the associated emission point.
- B. NSPS and NESHAP Requirements for PHARMA 1, EP-308
 - (1) The owner or operator shall comply with the applicable requirements in 40 CFR Part 63, Subpart VVVVVV §63.11494 – §63.11502], including those not specifically mentioned in this permit.
 - (a) The owner or operator shall comply with the applicable management practices as set forth in §63.11495 of Subpart VVVVVV, including, but not limited to:
 - (i) Equip each process vessel with a cover or lid that shall always be closed

when it is in HAP service, except for manual operations that require access, such as material addition and removal, inspection, sampling, and cleaning.

- (ii) Control total organic HAP emissions from transfer of liquids containing Table 1 organic HAP to tank trucks or railcars using any of the methods listed in §63.11495(a)(2)(i) through (iv).
- (iii) Conduct inspections of process vessels and equipment for each chemical manufacturing process unit (CMPU)¹ in HAP service, as specified in §63.11495(a)(3)(i) through (v).
- (iv) Repair any leak with 15 calendar days after detection of the leak or document the reason for any delay of repair. A leak shall be considered “repaired” if a condition specified in §63.11495(a)(4)(i), (ii) or (iii) is met.
- (v) Keep records of the dates and results of each inspection event, the dates of equipment repairs, and, if applicable, the reasons for any delay in repair.
- (b) The owner or operator shall comply with the applicable standards and compliance requirements for batch process vents as set forth in §63.11496 of Subpart VVVVVV, including, but not limited to:
 - (i) Demonstrate compliance with the requirements in §63.11496(a)(1) through (4) for organic HAP emissions from each batch process at the Pharma 1 Production Facility using Table 1 organic HAP.
 - (ii) Demonstrate compliance with the emission limits and other requirements in Table 2 to Subpart VVVVVV if uncontrolled organic HAP emissions from all batch process vents from a CMPU at the Pharma 1 Production Facility are equal to or greater than 10,000 pounds per year.
- (c) The owner or operator shall comply with the applicable standards and compliance requirements for wastewater systems as set forth in §63.11498 of Subpart VVVVVV, including, but not limited to:
 - (i) Demonstrate compliance with the applicable requirements in §63.11498(a) and in Table 6 for all wastewater streams at the Pharma 1 Production Facility subject to Subpart VVVVVV.
 - (ii) Determine the total concentration of partially soluble HAP in each wastewater stream using process knowledge, engineering assessment, or test data.
 - a. If the owner or operator makes any process or operational change that affects the concentration of partially soluble HAP in a wastewater stream, the concentration of partially soluble HAP shall be reevaluated.
- (d) The owner or operator shall comply with the applicable notification, recordkeeping, and reporting requirements as set forth in §63.11501 of Subpart VVVVVV.

C. VOC and HAP Emissions Calculations Requirements for PHARMA 1, EP-308

- (1) The owner or operator shall determine uncontrolled VOC and HAP emission rates from the process equipment covered by this permit by using one of the following methods:
 - (a) The owner or operator shall use the appropriate equations in 40 CFR

¹ Per 40 CFR §63.11502, a CMPU means “all equipment which collectively functions to produce a product or isolated intermediate. A process includes, but it is not limited to any, all, or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a product or isolated intermediate.”

- §63.1257(d)(2)(i) of Subpart GGG (*National Emission Standards for Pharmaceuticals Production*) to determine emissions from pharmaceutical production episodes such as displacement, purging, heating, depressurization, gas evolution, air drying, and empty vessel purging.
- (b) The owner or operator shall use the appropriate estimation methods in 40 CFR §63.1257(d)(2)(ii) of Subpart GGG (*National Emission Standards for Pharmaceuticals Production*) to determine emissions from other pharmaceutical production episodes.
 - (c) The owner or operator shall use appropriate resources, including “Methods for Estimating Air Emissions from Chemical Manufacturing Facilities” and the “pharmaceutical MACT” to determine emissions from non-pharmaceutical production.
 - (d) Where no U.S. EPA emission calculations are applicable, the owner or operator shall use standard engineering principles to best represent emissions from non-pharmaceutical production.
- (2) The owner or operator shall develop and document uncontrolled VOC emission factors (E_{fVOC}), in pounds of VOC per pound of product and uncontrolled Single HAP emission factors (E_{fSHAP}), in pounds of Single HAP per pound of product, to determine VOC and HAP emissions from the operation of the process equipment covered by this permit, including emissions from equipment leaks.
- (a) The calculation of each emission factor shall be subject to the review and approval of the Department. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, during the production of a specific final product to confirm the accuracy of the emission factor.
- (3) The owner or operator shall maintain the following monthly records for each batch run in the process equipment covered by this permit:
- (a) The identification and amount (gallons or pounds) of all materials used in the development of the emission factors for determining the emission rates from the process equipment covered by this permit.
 - (b) The identification and quantity of each final product generated.
- (4) The owner shall calculate monthly VOC emissions, in tons, emitted from the process equipment covered by this permit using the following equation:

Monthly VOC Emissions:

$$VOC_{Month(EP-308)} = \sum[(E_{fVOC} \times PP_{Month})] * (1 \text{ ton}/2000 \text{ pounds})]$$

Where:

$VOC_{Month(EP-308)}$ = Total tons of VOC emitted each month through EP-308

E_{fVOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP_{Month} = Pounds of each product generated per process each month

- (5) The owner or operator shall record the total monthly ($VOC_{Month(EP-308)}$) VOC emissions, in tons, from the operation of the process equipment covered by this permit.

- (6) The owner or operator shall calculate monthly emissions, in tons, for each Single HAP emitted from the process equipment covered by this permit using the following equation:

Monthly Single HAP Emissions:

$$SHAP_{\text{Month(EP-308)}} = \sum[(E_{f\text{SHAP}} \times PP_{\text{Month}})] * (1 \text{ ton}/2000 \text{ pounds})]$$

Where:

$SHAP_{\text{Month(EP-308)}}$ = Total tons of SHAP emitted each month through EP-308

$E_{f\text{SHAP}}$ = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Month} = Pounds of each product generated per process each month

- (7) The owner or operator shall record the monthly ($SHAP_{\text{Month(EP-308)}}$) emissions, in tons, for each Single HAP (SHAP) from the operation of the process equipment covered by this permit.
- (8) The owner or operator shall calculate monthly Total HAP emissions, in tons, emitted from the process equipment and storage tanks covered by this permit using the following equation:

Monthly Total HAP Emissions:

$$THAP_{\text{Month(EP-308)}} = \sum(\text{Monthly Emissions} \left(\frac{\text{tons}}{\text{month}} \right) \text{ for each Single HAP})$$

Where:

$THAP_{\text{Month(EP-308)}}$ = Total tons of Total HAP emitted each month through EP-308

- (9) The owner or operator shall record the total monthly ($THAP_{\text{Month(EP-303)}}$) Total HAP emissions, in tons, from the operation of the process equipment and storage tanks covered by this permit.

Facility-wide General Requirements

- D. The facility-wide emission limits (VOC, Single HAP, and Total HAP) listed in Permit Condition 1 shall apply to all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015.
- E. The owner or operator shall determine uncontrolled VOC and HAP emission rates from all the process equipment operating (including emissions from equipment leaks) at Plant No. 34-01-015 by using one of the following methods:
- (1) The owner or operator shall use the appropriate equations in 40 CFR §63.1257(d)(2)(i) of Subpart GGG (*National Emission Standards for Pharmaceuticals Production*) to determine emissions from pharmaceutical

- production episodes such as displacement, purging, heating, depressurization, gas evolution, air drying, and empty vessel purging.
- (2) The owner or operator shall use the appropriate estimation methods in 40 CFR §63.1257(d)(2)(ii) of Subpart GGG (*National Emission Standards for Pharmaceuticals Production*) to determine emissions from other pharmaceutical production episodes.
 - (3) The owner or operator shall use appropriate resources, including “Methods for Estimating Air Emissions from Chemical Manufacturing Facilities” and the “pharmaceutical MACT” to determine emissions from non-pharmaceutical production.
 - (4) Where no U.S. EPA emission calculations are applicable, the owner or operator shall use standard engineering principles to best represent emissions from non-pharmaceutical production.
- F. The owner or operator shall develop and document uncontrolled VOC emission factors (E_{fVOC}), in pounds of VOC per pound of product and uncontrolled Single HAP emission factors (E_{fSHAP}), in pounds of Single HAP per pound of product, to determine VOC and HAP emissions from the operation of each process equipment operating at Plant No. 34-01-015, including all emissions from equipment leaks.
- (1) The calculation of each emission factor shall be subject to the review and approval of the Department. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, during the production of a specific final product to confirm the accuracy of the emission factor.
- G. The owner or operator shall maintain the following monthly records for each batch run in every process equipment operating at Plant No. 34-01-015:
- (1) The identification and amount (gallons or pounds) of all materials used in the development of the emission factors for determining the emission rates from each process equipment operating at Plant No. 34-01-015.
 - (2) The identification and quantity of each final product generated.
- H. The owner or operator shall maintain monthly records of the controlled VOC and HAP emission rates for each batch of chemicals processed in each process equipment operating at Plant No. 34-01-015.
- (1) The owner or operator shall determine the controlled vent emission rates by using the applicable control efficiencies described in each applicable construction permit.
- I. The owner or operator shall use the appropriate equations and methods in EPA’s most recent Chapter 7 of EPA’s AP-42 (Compilation of Air Pollution Emission Factors) to determine uncontrolled VOC and HAP emissions from each storage tank operating at Plant No. 34-01-015
- J. The owner or operator shall maintain monthly records as described in the permits issued to the wastewater treatment plant, the boilers, and the non-emergency generators, respectively.

Facility-wide VOC Emissions Limit Requirements

- K. The total amount of VOC emitted from all the chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall not exceed 98 tons in any 12-month rolling period.

- (1) The owner or operator shall calculate the total amount, in tons, of VOC emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant Number 34-01-015 using the following equation:

$$\text{VOC}_{(\text{Facility})} = \text{VOC}_{(\text{Chem})} + \text{VOC}_{(\text{Storage})} + \text{VOC}_{(\text{WWTP})} + \text{VOC}_{(\text{Boilers})} + \text{VOC}_{(\text{Gen})}$$

Where:

$\text{VOC}_{(\text{Facility})}$ = Total tons of VOC emitted at Plant No. 34-01-015

$\text{VOC}_{(\text{Chem})} = \sum[(\text{Ef}_{\text{VOC}} \times \text{PP}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$

Where:

$\text{VOC}_{(\text{Chem})}$ = Total tons of VOC emitted from all the chemical processes (including emissions from equipment leaks) at Plant No. 34-01-015

Ef_{VOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP = Pounds of each product generated per process

Applicable Control Efficiency = [(Percent efficiency of the control equipment listed in the construction permit for the emission point) / 100] (Zero for process steps with no control)

$\text{VOC}_{(\text{Storage})}$ = Total tons of VOC emitted from all the storage tanks at Plant No. 34-01-015 as determined using the most recent Chapter 7 of EPA's AP-42

$\text{VOC}_{(\text{WWTP})}$ = Total tons of VOC emitted from the wastewater treatment plant as determined using the procedures in the permit.

$\text{VOC}_{(\text{Boilers})}$ = Total tons of VOC emitted from the boilers as determined using the procedures in each applicable permit

$\text{VOC}_{(\text{Gen})}$ = Total tons of VOC emitted from the non-emergency generators using the procedures in each applicable permit.

- (2) The owner or operator shall record the total monthly amount, in tons, of VOC emitted from all chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015. The owner or operator shall calculate the total monthly VOC emissions using the equation in Permit Condition 5.K.(1).
 - (3) The owner or operator shall calculate and record the total amount, in tons, of VOC emitted from all chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015 on a rolling 12-month basis.
- L. If the 12-month rolling total amount of VOC emitted at Plant Number 34-01-015 exceeds 78.4 tons, the owner or operator shall immediately begin calculating daily VOC emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant Number 34-01-015.

- (1) The following requirements apply to the daily VOC emissions calculations associated with the chemical processes (including emissions from equipment leaks) at Plant Number 34-01-015.
 - (a) The owner or operator may use the facility's emission inventory software (Emissions Accountant) to establish the daily emissions for the 12-month rolling period preceding the onset of daily emission recordkeeping.
 - (i) The daily emission data for the previous 12 months (prior to onset) shall be an average of the monthly production data input to the facility's emissions accounting data system.
 - (b) The owner or operator shall maintain the following records:
 - (i) The identification and quantity (pounds) of each product scheduled to be generated during each calendar year and the corresponding VOC emissions, in tons.
 - (ii) The projected total amount of VOC emissions for each product, in tons.
 - (iii) The projected total amount of VOC emissions for all products combined, in tons
 - (c) The projected emissions totals shall be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors shall be added once their respective batch record is finalized.
 - (d) Projected emissions shall be totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The owner or operator shall enter the actual production data within 15 days of batch completion.
- (2) The following requirements apply to the daily VOC emissions calculations from the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015.
 - (a) The owner or operator shall assume the worst-case scenario for each source, i.e., the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators, based on data from the available 12-month period preceding the onset of daily emission recordkeeping.
 - (i) The daily emission data for the previous 12 months (prior to onset) shall be the worst-case monthly emission values for each source averaged over the days in that month.
 - a. The owner or operator shall determine the worst-case monthly emission values for the wastewater treatment plant, the boilers, and the non-emergency generators using the month with the highest combined VOC emissions.
 - b. The owner or operator shall determine the worst-case monthly emission values for the storage tanks on a tank-by-tank basis.
 - (ii) After each respective month is completed, the actual emissions will supersede the projected emissions. The actual daily emissions shall be calculated by averaging the actual emissions from that month for each source, using the procedures in each applicable permit, over the days in that month. The owner or operator shall enter the actual emissions data within 15 days of the end of the month.

- (3) The owner or operator shall record the total daily amount, in tons, of VOC emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015. The owner or operator shall calculate total daily VOC emissions using the equation in Permit Condition 5.K.(1).
- (4) The owner or operator shall revise the daily VOC emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators when monthly emission data is available.
- (5) Daily emission calculations and recordkeeping of VOC emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall continue until the rolling 12-month total VOC emissions from the facility drops below 78.4 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of VOC emissions from these sources shall cease.

Facility-wide Single HAP Emissions Limit Requirements

M. The total amount of each Single HAP (SHAP) emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, wastewater treatment plant, boilers, and non-emergency generators operating at Plant No. 34-01-015 shall not exceed 9.4 tons in any 12-month rolling period.

- (1) The owner or operator shall calculate the total amount, in tons, of each SHAP emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No.34-01-015 using the following equation:

$$\text{SHAP}_{(\text{Facility})} = \text{SHAP}_{(\text{Chem})} + \text{SHAP}_{(\text{Storage})} + \text{SHAP}_{(\text{WWTP})} + \text{SHAP}_{(\text{Boilers})} + \text{SHAP}_{(\text{Gen})}$$

Where:

$\text{SHAP}_{(\text{Facility})}$ = Total tons of SHAP emitted at Plant No. 34-01-015

$\text{SHAP}_{(\text{Chem})} = \sum[(\text{Ef}_{\text{SHAP}} \times \text{PP}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$

Where:

$\text{SHAP}_{(\text{Chem})}$ = Total tons of SHAP emitted from all the chemical processes (including emissions from equipment leaks) at Plant No. 34-01-015

Ef_{SHAP} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP = Pounds of each product generated per process

Applicable Control Efficiency = [(Percent efficiency of the control equipment listed in the construction permit for the emission point) / 100] (Zero for process steps with no control)

$\text{SHAP}_{(\text{Storage})}$ = Total tons of SHAP emitted from all the storage tanks at

Plant No. 34-01-015 as determined using the most recent Chapter 7 of EPA's AP-42

$SHAP_{(WWTP)}$ = Total tons of SHAP emitted from the wastewater treatment plant as determined using the procedures in the permit.

$SHAP_{(Boilers)}$ = Total tons of SHAP emitted from the boilers as determined using the procedures in each applicable permit

$SHAP_{(Gen)}$ = Total tons of SHAP emitted from the non-emergency generators using the procedures in each applicable permit.

- (2) The owner or operator shall record the total monthly amount, in tons, of each SHAP emitted from all the chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015. The owner or operator shall calculate the total monthly SHAP emissions using the equation in Permit Condition 5.M.(1).
 - (3) The owner or operator shall calculate and record the total amount, in tons, of each SHAP emitted from all the chemical processes (including emissions from equipment leaks), storage tanks, wastewater treatment plant, boilers, and non-emergency generators at Plant No. 34-01-015 on a rolling 12-month basis.
- N. If the 12-month rolling total amount of SHAP emitted at Plant Number 34-01-015 exceeds 7.5 tons, the owner or operator shall immediately begin calculating daily SHAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015.
- (1) The following requirements apply to the daily SHAP emissions calculations associated with the chemical processes (including emissions from equipment leaks) at Plant Number 34-01-015.
 - (a) The owner or operator may use the facility's emission inventory software (Emissions Accountant) to establish the daily emissions for the 12-month rolling period preceding the onset of daily emission recordkeeping.
 - (i) The daily emission data for the previous 12 months (prior to onset) shall be an average of the monthly production data input to the facility's emissions accounting data system,
 - (b) The owner or operator shall maintain the following records:
 - (i) The identification and quantity (pounds) of each product scheduled to be generated during each calendar year and the corresponding SHAP emissions, in tons.
 - (ii) The projected total amount of SHAP emissions for each product, in tons.
 - (iii) The projected total amount of SHAP emissions for all products combined, in tons.
 - (c) The projected emissions totals shall be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors shall be added once their respective batch record is finalized.
 - (d) Projected emissions shall be totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The owner or operator shall enter the production data within 15

- days of batch completion.
- (2) The following requirements apply to the daily SHAP emissions calculations from the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015.
 - (a) The owner or operator may assume the worst-case scenario for each source, i.e., the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators, based on data from the available 12-month period preceding the onset of daily emission recordkeeping.
 - (i) The daily emission data for the previous 12 months (prior to onset) shall be the worst-case monthly emission values for each source averaged over the days in that month.
 - a. The owner or operator shall determine the worst-case monthly emission values for the wastewater treatment plant, the boilers, and the non-emergency generators using the month with the highest combined emissions for each Single HAP.
 - b. The owner or operator shall determine the worst-case monthly emission values for the storage tanks on a tank-by-tank basis.
 - (b) After each respective month is completed, the actual emissions will supersede the projected emissions. The actual daily emissions shall be calculated by averaging the actual emissions from that month for each source, using the procedures in each applicable permit, over the days in that month. The owner or operator shall enter the actual emissions data within 15 days of the end of the month.
 - (3) The owner or operator shall record the total daily amount, in tons, of each SHAP emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015. The owner or operator shall calculate the total daily SHAP emissions using the equation in Permit Condition 5.M.(1).
 - (4) The owner may revise the daily SHAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators when monthly emissions are available.
 - (5) Daily emission calculations and recordkeeping of SHAP emissions from the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall continue until the rolling 12-month total SHAP emissions from the facility drops below 7.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of SHAP emissions from these sources shall cease.

Facility-wide Total HAP Emissions Limit Requirements

- O. The total amount of Total HAP (THAP) emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall not exceed 24.4 tons in any 12-month rolling period.
 - (1) The owner or operator shall calculate the total amount, in tons, of THAP emitted from all the chemical processes (including emissions from equipment leaks), all

storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 using the following equation:

$$THAP_{(Facility)} = \sum (Total\ Emissions\ for\ each\ Single\ HAP)_{All\ Sources}$$

Where:

$THAP_{(Facility)}$ = Total tons of Total HAP emitted at Plant No. 34-01-015

- (2) The owner or operator shall record the total monthly amount, in tons, of THAP emitted from all the chemical processes (including equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015. The owner or operator shall calculate the monthly THAP emissions using the equation in Permit Condition 5.O.(1).
 - (3) The owner or operator shall calculate and record the amount, in tons, of THAP emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 on a rolling 12-month basis.
- P. If the 12-month rolling total amount of THAP emitted at Plant Number 34-01-015 exceeds 19.5 tons, the owner or operator shall immediately begin calculating daily THAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators operating at Plant No. 34-01-015.
- (1) The following requirements apply to the daily THAP emissions calculations associated with all chemical processes (including emissions from equipment leaks) at Plant No. 34-01-015.
 - (a) The owner or operator may use the facility's emission inventory software (Emissions Accountant) to establish the daily emissions for the 12-month rolling period preceding the onset of daily emission recordkeeping.
 - (i) The daily emission data for the previous 12 months (prior to onset) shall be an average of the monthly production data input to the facility's emissions accounting data system.
 - (b) The owner or operator shall maintain the following records:
 - (i) The identification and quantity (pounds) of each product scheduled to be generated during each calendar year and the corresponding THAP emissions, in tons.
 - (ii) The projected total amount of THAP emissions for each product, in tons.
 - (iii) The projected total amount of THAP emissions for all products combined, in tons.
 - (c) The projected emissions totals shall be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors shall be added once their respective batch record is finalized.
 - (d) Projected emissions shall be totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The owner or operator shall enter the actual production data within 15 days of batch completion.

- (2) The following requirements apply to the daily THAP emissions calculations from the storage tanks, wastewater treatment plant, boilers, and non-emergency generators at Plant No. 34-01-015.
 - (a) The owner or operator may assume the worst-case scenario for each source, i.e., the storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators, based on data from the available 12-month period preceding the onset of daily emission recordkeeping.
 - (i) The daily emission data for the previous 12 months (prior to onset) shall be the worst-case monthly emission values for each source averaged over the days in that month.
 - a. The owner or operator shall determine the worst-case monthly emission values for the wastewater treatment plant, the boilers, and the non-emergency generators using the month with the highest combined THAP emissions.
 - b. The owner or operator shall determine the worst-case monthly emission values for the storage tanks on a tank-by-tank basis.
 - (b) After each respective month is completed, the actual emissions will supersede the projected emissions. The actual daily emissions shall be calculated by averaging the actual emissions from that month for each source, using the procedures in each applicable permit, over the days in that month. The owner or operator shall enter the actual emissions data within 15 days of the end of the month.
 - (3) The owner or operator shall record the total daily amount, in tons, of THAP emitted from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015. The owner or operator shall calculate the daily THAP emissions using the equation in Permit Condition 5.O.(1).
 - (4) The owner may revise the daily THAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators when monthly emissions are available.
 - (5) Daily emission calculations and recordkeeping of THAP emissions from all the chemical processes (including emissions from equipment leaks), all storage tanks, the wastewater treatment plant, the boilers, and the non-emergency generators at Plant No. 34-01-015 shall continue until the rolling 12-month THAP emissions from the facility drops below 19.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of THAP emissions from these sources shall cease.

Facility-wide VOC and HAP Emissions Reporting Requirements

- Q. The owner or operator shall submit semi-annual reports on VOC and HAP emissions, in tons, from all operations at Plant Number 34-01-015.
 - (1) These reports shall contain the following information:
 - (a) Facility-wide VOC emissions, in tons, for each month in the reporting period.
 - (b) Facility-wide emissions, in tons, of each Single HAP for each month in the reporting period.

- (c) Facility-wide Total HAP emissions, in tons, for each month in the reporting period.
- (2) These reports shall be submitted by August 1 and February 1 of each year. The August report shall cover January through June and the February report shall cover July through December.
- R. The owner or operator shall submit deviation reports that identify all exceedances of the rolling 12-month emission limitations for VOC, Single HAP, and Total HAP.
 - (1) The owner or operator shall submit the report no later than 30 days from the end of the month in which the exceedance occurred.

Authority for Requirement: DNR Construction Permit 14-A-626-S2

Emission Point Characteristics

The emission point shall conform to the specifications listed below.

Stack Height, (ft, from the ground): 54

Stack Opening, (inches, dia.): 2

Exhaust Flow Rate (scfm): 0 - 32

Exhaust Temperature (°F): 0 - 74

Discharge Style: Vertical obstructed

Authority for Requirement: DNR Construction Permit 14-A-626-S2

The temperature and flowrate are intended to be representative and characteristic of the design of the permitted emission point. The Department recognizes that the temperature and flow rate may vary with changes in the process and ambient conditions. If it is determined that either the temperature or flowrate above are different than the values stated, the owner or operator shall submit a request to the Department within thirty (30) days of the discovery to determine if a permit amendment is required or submit a permit application requesting to amend the permit.

Monitoring Requirements

The owner/operator of this equipment shall comply with the monitoring requirements listed below.

Agency Approved Operation & Maintenance Plan Required? Yes ☐ No ☒

Facility Maintained Operation & Maintenance Plan Required? Yes ☐ No ☒

Compliance Assurance Monitoring (CAM) Plan Required? Yes ☐ No ☒

Authority for Requirement: 567 IAC 22.108(3)

Emission Point ID Number: EP 309

Associated Equipment

Emission Unit	Emission Unit Description	Raw Material	Rated Capacity	Construction Permit
R-3701	Reactor	Pharmaceutical Raw Materials	500 gallons	19-A-067
R-3702	Reactor		500 gallons	
R-3703	Reactor		500 gallons	
R-3701-T-0103	Tank		10 gallons	
R-3702-T-0203	Tank		10 gallons	
R-3703-T-0303	Tank		10 gallons	
T-3704	Tank		100 gallons	
T-3705	Tank		300 gallons	
T-3712	Tank		40 gallons	
T-3713	Tank		40 gallons	
T-3715	Tank		300 gallons	

Applicable Requirements

Emission Limits (lb./hr, gr./dscf, lb./MMBtu, % opacity, etc.)

The emissions from this emission point shall not exceed the levels specified below.

See "Plant-Wide Conditions" for applicable emission limits.

NESHAP Applicability

This facility is of the source type regulated under the National Emission Standard for Hazardous Air Pollutants (NESHAP) for Chemical Manufacturing Area Sources (40 CFR 63 Subpart VVVVVV) and 40 CFR 63 Subpart A – General Provisions.

Authority for Requirement: 40 CFR 63 Subpart A
567 IAC 23.1(4)
40 CFR 63 Subpart VVVVVV
567 IAC 23.1(4)"ev"
DNR Construction Permit 19-A-067

Operating Requirements with Associated Monitoring and Recordkeeping

All records as required by this permit shall be kept on-site for a minimum of five (5) years and shall be available for inspection by the Department. Records shall be legible and maintained in an orderly manner. The operating requirements and associated recordkeeping for this permit shall be:

GENERAL REQUIREMENTS

- A. The owner or operator shall maintain the following records for each batch run in the equipment covered by this permit:

- i. The identification and amount (gallons or pounds) of all materials used in the development of the emission factors for the purpose of determining the emission rates from the equipment covered by this permit.
 - ii. The identification and quantity (pounds) of each product generated.
- B. The owner or operator shall develop and document uncontrolled VOC emission factors (E_{fVOC}), in pounds of VOC per pound of product and uncontrolled Single HAP emission factors (E_{fSHAP}), in pounds of Single HAP per pound of product, to determine VOC and HAP emissions from the production of each final product using the equipment listed in Construction Permit Condition 3b.
 - i. The calculation of each emission factor shall be subject to the review and approval of the Department. If necessary, the owner or operator shall conduct emission testing, at the request of the Department, during the production of a specific product to confirm the accuracy of the emission factor.
- C. The owner or operator shall determine uncontrolled VOC and HAP emission rates by using one the following methods:
 - (1) For pharmaceutical products, for emissions from vapor displacement, purging, heating, depressurization, gas evolution, air drying, and empty vessel purging, the appropriate equations from 40 CFR §63.1257(d)(2)(i) of Subpart GGG (*National Emission Standards for Pharmaceuticals Production*), also known as “pharmaceutical MACT,” shall be used.
 - (2) For other emission episodes in the production of pharmaceutical products, appropriate estimation methods as stated in 40 CFR §63.1257(d)(2)(i) of Subpart GGG shall be used.
 - (3) For non-pharmaceutical products, appropriate resources, including “Methods for Estimating Air Emissions from Chemical Manufacturing Facilities” and the “pharmaceutical MACT” shall be used.
 - (4) For breathing and working losses from storage tanks, the appropriate equations and methods provided in EPA’s most recent AP-42 (Compilation of Air Pollutant Emission Factors) shall be used.
 - (5) For non-pharmaceutical products where no U.S. EPA emission calculations are applicable, standard engineering principles shall be used to best represent the emission rate from the unit.
- D. The owner or operator shall use and update, as needed, the procedures developed to calculate VOC, Single HAP, and Total HAP daily emissions. These procedures shall be implemented if and when the 12-month rolling total for VOC, Single HAP, and Total HAP reaches 78.4 tons, 7.5 tons, and 19.5 tons, respectively (see Construction Permit Conditions 5.L, 5.N, and 5.P).
 - i. At a minimum, the procedures shall include the following:
 - i. Methodology to be followed and an explanation of how the selected methodology will reliably determine daily emissions.
 - ii. Description of the time needed to compile the information needed to complete the daily emissions calculations.
 - iii. Description of the records needed to perform daily emissions calculations.

VOC EMISSIONS CALCULATIONS REQUIREMENTS for EQUIPMENT in this EMISSION POINT

- E. The owner shall calculate monthly VOC emissions, in tons, using the following equation:

Monthly VOC Emissions:

$$\text{VOC}_{\text{Month(c)}} = \sum[(\text{Ef}_{\text{VOC}} \times \text{PP}_{\text{Month}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{VOC}_{\text{Month(c)}}$ = Total tons of VOC emitted each month

Ef_{VOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP_{Month} = Pounds of each product generated per process each month

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- F. The owner or operator shall record the total monthly ($\text{VOC}_{\text{Month(c)}}$) VOC emissions, in tons, from the production of each product using the equipment listed in Construction Permit Condition 3b.

SINGLE HAP EMISSIONS CALCULATIONS REQUIREMENTS for EQUIPMENT in this EMISSION POINT

- G. The owner or operator shall calculate monthly emissions, in tons, for each Single HAP using the following equations:

Monthly Single HAP Emissions:

$$\text{SHAP}_{\text{Month(c)}} = \sum[(\text{Ef}_{\text{SHAP}} \times \text{PP}_{\text{Month}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{SHAP}_{\text{Month(c)}}$ = Total tons of Single HAP (SHAP) emitted each month

Ef_{SHAP} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Month} = Pounds of each product generated per process each month

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- H. The owner or operator shall record the monthly ($\text{SHAP}_{\text{Month(c)}}$) emissions, in tons, for each Single HAP (SHAP) from the production of each product using the equipment listed in Construction Permit Condition 3b.

TOTAL HAP EMISSIONS CALCULATIONS REQUIREMENTS for EQUIPMENT in this EMISSION POINT

- I. The owner or operator shall calculate monthly Total HAP emissions, in tons, using the following equations:

- iii. Monthly Total HAP Emissions:

$$THAP_{Month(c)} = \sum (Monthly \text{ Emissions } (\frac{tons}{month}) \text{ for each Single HAP})$$

Where:

$THAP_{Month(c)}$ = Total tons of Total HAP emitted each month

- J. The owner or operator shall record the total monthly ($THAP_{Month(c)}$) Total HAP emissions, in tons, from the production of each product using the equipment listed in Construction Permit Condition 3b by using Single HAP emissions as indicated in Construction Permit Condition 5.G.

FACILITY-WIDE VOC EMISSIONS LIMIT REQUIREMENTS

- K. The total amount of VOC emitted, facility-wide, at Plant Number 34-01-015 shall not exceed 98 tons in any 12-month rolling period.
- (3) The owner or operator shall record the total amount, in tons, of VOC emitted from all sources (e.g., chemical processes, combustion, tanks, wastewater, etc.) at Plant Number 34-01-015 on a monthly basis.
 - (4) The owner or operator shall calculate and record the total amount, in tons, of VOC emitted from all sources at Plant Number 34-01-015 on a rolling 12-month basis.
- L. If the 12-month rolling total amount of VOC emitted at the facility (Plant Number 34-01-015) exceeds 78.4 tons, the permittee shall immediately begin calculating the daily emissions from the chemical processes. The following records and procedures shall be used:
- (1) The identification and quantity (pounds) of each product scheduled to be generated during each calendar day and the corresponding VOC emissions, in tons.
 - (2) The projected total amount of VOC emissions for each product, in tons.
 - (3) The projected total amount of VOC emissions for all products combined, in tons.
 - (4) The 365-day rolling total amount of VOC emissions for all products produced in the chemical processes, in tons.
 - (5) The facility is not required to retroactively determine daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The facility may use its emissions accounting software (i.e., data system) to establish the daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The daily data from the previous 12-months (prior to onset) will be an average of the monthly production data input to the facility's emissions accounting data system.
 - (6) The projected emission totals will be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors will be added once their respective batch record is finalized.
 - (7) Projected emissions are totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The actual production data will be entered within 15 days of batch completion.
 - (8) The owner or operator shall calculate daily VOC emissions from the chemical processes at Plant Number 34-01-015 using the following equation:

$$VOC_{Day(c)} = \sum [(Ef_{VOC} \times PP_{Day}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$VOC_{Day(c)}$ = Total tons of VOC emitted each day from the chemical

processes

E_{fVOC} = Process-specific emission factor for VOC (lb VOC / lb product)

PP_{Day} = Pounds of each product generated per process each day

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- (9) Daily emission calculations and recordkeeping of VOC emissions from the chemical processes at Plant Number 34-01-015 shall continue until the rolling 12-month total VOC emissions from the facility drops below 78.4 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of VOC emissions from the chemical processes shall cease.

FACILITY-WIDE SINGLE HAP EMISSIONS LIMIT REQUIREMENTS

M. The total amount for each Single HAP (SHAP) emitted at Plant Number 34-01-015 shall not exceed 9.4 tons in any 12-month rolling period.

- (1) The owner or operator shall record the total amount, in tons, of each Single HAP (SHAP) emitted from all sources (e.g., chemical processes, combustion, tanks, wastewater, etc.) at Plant Number 34-01-015 on a monthly basis.
- (2) The owner or operator shall calculate and record the total amount, in tons, of each Single HAP (SHAP) emitted from all sources at Plant Number 34-01-015 on a rolling 12-month basis.

N. If the 12-month rolling total amount of any SHAP emitted at the facility (Plant Number 34-01-015) exceeds 7.5 tons, the permittee shall immediately begin calculating the daily emissions from the chemical processes. The following records and procedures shall be used:

- (1) The identification and quantity (pounds) of each product scheduled to be generated during each calendar day and the corresponding SHAP emissions, in tons.
- (2) The projected total amount of SHAP emissions for each product, in tons.
- (3) The projected total amount of SHAP emissions for all products combined, in tons.
- (4) The 365-day rolling total amount of SHAP emissions for all products produced in the chemical processes, in tons.
- (5) The facility is not required to retroactively determine daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The facility may use its emissions accounting software (i.e., data system) to establish the daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The daily data from the previous 12-months (prior to onset) will be an average of the monthly production data input to the facility's emissions accounting data system.
- (6) The projected emission totals will be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors will be added once their respective batch record is finalized.
- (7) Projected emissions are totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The actual production data will be entered within 15 days of batch completion.
- (8) The owner or operator shall calculate daily SHAP emissions from the chemical

processes at Plant Number 34-01-015 using the following equation:

$$\text{SHAP}_{\text{Day(c)}} = \sum[(\text{Ef}_{\text{SHAP}} \times \text{PP}_{\text{Day}}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$\text{SHAP}_{\text{Day(c)}}$ = Total tons of SHAP emitted each day from the chemical processes

Ef_{SHAPC} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Day} = Pounds of each product generated per process each day

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- (9) Daily emission calculations and recordkeeping of SHAP emissions from the chemical processes at Plant Number 34-01-015 shall continue until the rolling 12-month total SHAP emissions from the facility drops below 7.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of SHAP emissions from the chemical processes shall cease.

FACILITY-WIDE TOTAL HAP EMISSIONS LIMIT REQUIREMENTS

O. The total amount of Total HAPs (THAPs) emitted at Plant Number 34-01-015 shall not exceed 24.4 tons in any 12-month rolling period.

- (1) The owner or operator shall record the total amount, in tons, of Total HAP (THAP) emitted from all sources (e.g., chemical processes, combustion, tanks, wastewater, etc.) at Plant Number 34-01-015 on a monthly basis.
- (2) The owner or operator shall calculate and record the total amount, in tons, of Total HAP (THAP) emitted from all sources at Plant Number 34-01-015 on a rolling 12-month basis.

P. If the 12-month rolling total amount of THAP emitted at the facility (Plant Number 34-01-015) exceeds 19.5 tons, the permittee shall immediately begin calculating the daily emissions from the chemical processes. The following records and procedures shall be used:

- (1) The identification and quantity (pounds) of each product scheduled to be generated during each calendar day and the corresponding THAP emissions, in tons.
- (2) The projected total amount of THAP emissions for each product, in tons.
- (3) The projected total amount of THAP emissions for all products combined, in tons.
- (4) The 365-day rolling total amount of THAP emissions for all products produced in the chemical processes, in tons.
- (5) The facility is not required to retroactively determine daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The facility may use its emissions accounting software (i.e., data system) to establish the daily emissions for the 12-month rolling period preceding the onset of daily recordkeeping. The daily data from the previous 12-months (prior to onset) will be an average of the monthly production data input to the facility's emissions accounting data system.

- (6) The projected emission totals will be based on the facility's (Plant Number 34-01-015) production schedule. Processes that require additional calculations to determine emission factors will be added once their respective batch record is finalized.
- (7) Projected emissions are totaled on the day the batch is projected to start. After the respective batch has completed, the actual yield will supersede the projected yield. The actual production data will be entered within 15 days of batch completion.
- (8) The owner or operator shall calculate daily SHAP emissions from the chemical processes at Plant Number 34-01-015 using the following equation:

$$THAP_{Day(c)} = \sum [(Ef_{THAP} \times PP_{Day}) * (1 \text{ ton}/2000 \text{ pounds}) * (1 - \text{Applicable Control Efficiency})]$$

Where:

$THAP_{Day(c)}$ = Total tons of SHAP emitted each day from the chemical processes

Ef_{THAP} = Process-specific emission factor for SHAP (lb SHAP / lb product)

PP_{Day} = Pounds of each product generated per process each day

Applicable Control Efficiency = [(Percent efficiency of the control equipment as specified in the construction permit for the emission point) / 100] (Zero for process steps with no control)

- (9) Daily emission calculations and recordkeeping of THAP emissions from the chemical processes at Plant Number 34-01-015 shall continue until the rolling 12-month total THAP emissions from the facility drops below 19.5 tons for that calendar month plus one additional calendar month, at which time, rolling daily calculations of SHAP emissions from the chemical processes shall cease.

VOC and HAP EMISSIONS REPORTING REQUIREMENTS

- Q. The owner or operator shall submit semi-annual reports on VOC and HAP emissions, in tons, from all operations at Plant Number 34-01-015.
 - (1) These reports shall contain the following information:
 - i. Facility-wide VOC emissions, in tons, for each month in the reporting period.
 - ii. Facility-wide emissions, in tons, of each Single HAP for each month in the reporting period.
 - iii. Facility-wide Total HAP emissions, in tons, for each month in the reporting period
 - (2) These reports shall be submitted by August 1 and February 1 of each year. The August report shall cover January through June and the February report shall cover July through December.
- R. The owner or operator shall submit deviation reports that identify all exceedances of the rolling 12-month emission limitations for VOC, Single HAP, and Total HAP.
 - (1) The owner or operator shall submit the report no later than 30 days from the end of the month in which the exceedance occurred.

Authority for Requirement: DNR Construction Permit 19-A-067

Emission Point Characteristics

The emission point shall conform to the specifications listed below.

Stack Height, (ft, from the ground): 54

Stack Opening, (inches, dia.): 2

Exhaust Flow Rate (scfm): 100 (max)

Exhaust Temperature (°F): 140 (max)

Discharge Style: Vertical obstructed

Authority for Requirement: DNR Construction Permit 19-A-067

The temperature and flowrate are intended to be representative and characteristic of the design of the permitted emission point. The Department recognizes that the temperature and flow rate may vary with changes in the process and ambient conditions. If it is determined that either the temperature or flowrate above are different than the values stated, the owner or operator shall submit a request to the Department within thirty (30) days of the discovery to determine if a permit amendment is required or submit a permit application requesting to amend the permit.

Monitoring Requirements

The owner/operator of this equipment shall comply with the monitoring requirements listed below.

Agency Approved Operation & Maintenance Plan Required? Yes ☐ No ☒

Facility Maintained Operation & Maintenance Plan Required? Yes ☐ No ☒

Compliance Assurance Monitoring (CAM) Plan Required? Yes ☐ No ☒

Authority for Requirement: 567 IAC 22.108(3)

IV. General Conditions

This permit is issued under the authority of the Iowa Code subsection 455B.133(8) and in accordance with 567 Iowa Administrative Code chapter 22.

G1. Duty to Comply

1. The permittee must comply with all conditions of the Title V permit. Any permit noncompliance constitutes a violation of the Act and is grounds for enforcement action; for a permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application. *567 IAC 22.108(9)"a"*
2. Any compliance schedule shall be supplemental to, and shall not sanction noncompliance with, the applicable requirements on which it is based. *567 IAC 22.105 (2)"h"(3)*
3. Where an applicable requirement of the Act is more stringent than an applicable requirement of regulations promulgated under Title IV of the Act, both provisions shall be enforceable by the administrator and are incorporated into this permit. *567 IAC 22.108 (1)"b"*
4. Unless specified as either "state enforceable only" or "local program enforceable only", all terms and conditions in the permit, including provisions to limit a source's potential to emit, are enforceable by the administrator and citizens under the Act. *567 IAC 22.108 (14)*
5. It shall not be a defense for a permittee, in an enforcement action, that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of the permit. *567 IAC 22.108 (9)"b"*
6. For applicable requirements with which the permittee is in compliance, the permittee shall continue to comply with such requirements. For applicable requirements that will become effective during the permit term, the permittee shall meet such requirements on a timely basis. *567 IAC 22.108(15)"c"*

G2. Permit Expiration

1. Except as provided in rule 567—22.104(455B), permit expiration terminates a source's right to operate unless a timely and complete application for renewal has been submitted in accordance with rule 567—22.105(455B). *567 IAC 22.116(2)*
2. To be considered timely, the owner, operator, or designated representative (where applicable) of each source required to obtain a Title V permit shall submit on forms or electronic format specified by the Department to the Air Quality Bureau, Iowa Department of Natural Resources, Air Quality Bureau, Wallace State Office Building, 502 E 9th St., Des Moines, IA 50319-0034, two copies (three if your facility is located in Linn or Polk county) of a complete permit application, at least 6 months but not more than 18 months prior to the date of permit expiration. An additional copy must also be sent to U.S. EPA Region VII, Attention: Chief of Air Permitting & Standards Branch, 11201 Renner Blvd., Lenexa, KS 66219. Additional copies to local programs or EPA are not required for application materials submitted through the electronic format specified by the Department. The application must include all emission points, emission units, air pollution control equipment, and monitoring devices at the facility. All emissions generating activities, including fugitive emissions, must be included. The definition of a complete application is as indicated in 567 IAC 22.105(2). *567 IAC 22.105*

G3. Certification Requirement for Title V Related Documents

Any application, report, compliance certification or other document submitted pursuant to this permit shall contain certification by a responsible official of truth, accuracy, and completeness. All certifications shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete. *567 IAC 22.107 (4)*

G4. Annual Compliance Certification

By March 31 of each year, the permittee shall submit compliance certifications for the previous calendar year. The certifications shall include descriptions of means to monitor the compliance status of all emissions sources including emissions limitations, standards, and work practices in accordance with applicable requirements. The certification for a source shall include the identification of each term or condition of the permit that is the basis of the certification; the compliance status; whether compliance was continuous or intermittent; the method(s) used for determining the compliance status of the source, currently and over the reporting period consistent with all applicable department rules. For sources determined not to be in compliance at the time of compliance certification, a compliance schedule shall be submitted which provides for periodic progress reports, dates for achieving activities, milestones, and an explanation of why any dates were missed and preventive or corrective measures. The compliance certification shall be submitted to the administrator, director, and the appropriate DNR Field office. *567 IAC 22.108 (15)"e"*

G5. Semi-Annual Monitoring Report

By March 31 and September 30 of each year, the permittee shall submit a report of any monitoring required under this permit for the 6 month periods of July 1 to December 31 and January 1 to June 30, respectively. All instances of deviations from permit requirements must be clearly identified in these reports, and the report must be signed by a responsible official, consistent with 567 IAC 22.107(4). The semi-annual monitoring report shall be submitted to the director and the appropriate DNR Field office. *567 IAC 22.108 (5)*

G6. Annual Fee

1. The permittee is required under subrule 567 IAC 22.106 to pay an annual fee based on the total tons of actual emissions of each regulated air pollutant. Beginning July 1, 1996, Title V operating permit fees will be paid on July 1 of each year. The fee shall be based on emissions for the previous calendar year.
2. The fee amount shall be calculated based on the first 4,000 tons of each regulated air pollutant emitted each year. The fee to be charged per ton of pollutant will be available from the department by June 1 of each year. The Responsible Official will be advised of any change in the annual fee per ton of pollutant.
3. The emissions inventory shall be submitted annually by March 31 with forms specified by the department documenting actual emissions for the previous calendar year.
4. The fee shall be submitted annually by July 1 with forms specified by the department.
5. If there are any changes to the emission calculation form, the department shall make revised forms available to the public by January 1. If revised forms are not available by January 1, forms from the previous year may be used and the year of emissions documented changed. The department shall calculate the total statewide Title V emissions for the prior calendar year and make this information available to the public no later than April 30 of each year.
6. Phase I acid rain affected units under section 404 of the Act shall not be required to pay a fee for emissions which occur during the years 1993 through 1999 inclusive.
7. The fee for a portable emissions unit or stationary source which operates both in Iowa and out of state shall be calculated only for emissions from the source while operating in Iowa.
8. Failure to pay the appropriate Title V fee represents cause for revocation of the Title V permit as indicated in 567 IAC 22.115(1)"d".

G7. Inspection of Premises, Records, Equipment, Methods and Discharges

Upon presentation of proper credentials and any other documents as may be required by law, the permittee shall allow the director or the director's authorized representative to:

1. Enter upon the permittee's premises where a Title V source is located or emissions-related activity is conducted, or where records must be kept under the conditions of the permit;
2. Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit;
3. Inspect, at reasonable times, any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under the permit; and
4. Sample or monitor, at reasonable times, substances or parameters for the purpose of ensuring compliance with the permit or other applicable requirements. *567 IAC 22.108 (15)"b"*

G8. Duty to Provide Information

The permittee shall furnish to the director, within a reasonable time, any information that the director may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee also shall furnish to the director copies of records required to be kept by the permit, or for information claimed to be confidential, the permittee shall furnish such records directly to the administrator of EPA along with a claim of confidentiality. *567 IAC 22.108 (9)"e"*

G9. General Maintenance and Repair Duties

The owner or operator of any air emission source or control equipment shall:

1. Maintain and operate the equipment or control equipment at all times in a manner consistent with good practice for minimizing emissions.
2. Remedy any cause of excess emissions in an expeditious manner.
3. Minimize the amount and duration of any excess emission to the maximum extent possible during periods of such emissions. These measures may include but not be limited to the use of clean fuels, production cutbacks, or the use of alternate process units or, in the case of utilities, purchase of electrical power until repairs are completed.
4. Schedule, at a minimum, routine maintenance of equipment or control equipment during periods of process shutdowns to the maximum extent possible. *567 IAC 24.2(1)*

G10. Recordkeeping Requirements for Compliance Monitoring

1. In addition to any source specific recordkeeping requirements contained in this permit, the permittee shall maintain the following compliance monitoring records, where applicable:

- a. The date, place and time of sampling or measurements
- b. The date the analyses were performed.
- c. The company or entity that performed the analyses.
- d. The analytical techniques or methods used.
- e. The results of such analyses; and
- f. The operating conditions as existing at the time of sampling or measurement.
- g. The records of quality assurance for continuous compliance monitoring systems (including but not limited to quality control activities, audits and calibration drifts.)

2. The permittee shall retain records of all required compliance monitoring data and support information for a period of at least 5 years from the date of compliance monitoring sample, measurement report or application. Support information includes all calibration and maintenance records and all original strip chart recordings for continuous compliance monitoring, and copies of all reports required by the permit.

3. For any source which in its application identified reasonably anticipated alternative operating scenarios, the permittee shall:

- a. Comply with all terms and conditions of this permit specific to each alternative scenario.
- b. Maintain a log at the permitted facility of the scenario under which it is operating.
- c. Consider the permit shield, if provided in this permit, to extend to all terms and conditions under each operating scenario. *567 IAC 22.108(4), 567 IAC 22.108(12)*

G11. Evidence used in establishing that a violation has or is occurring.

Notwithstanding any other provisions of these rules, any credible evidence may be used for the purpose of establishing whether a person has violated or is in violation of any provisions herein.

1. Information from the use of the following methods is presumptively credible evidence of whether a violation has occurred at a source:

- a. A monitoring method approved for the source and incorporated in an operating permit pursuant to 567 Chapter 22;
- b. Compliance test methods specified in 567 Chapter 25; or
- c. Testing or monitoring methods approved for the source in a construction permit issued pursuant to 567 Chapter 22.

2. The following testing, monitoring or information gathering methods are presumptively credible testing, monitoring, or information gathering methods:

- a. Any monitoring or testing methods provided in these rules; or
- b. Other testing, monitoring, or information gathering methods that produce information comparable to that produced by any method in subrule 21.5(1) or this subrule. *567 IAC 21.5(1)-567 IAC 21.5(2)*

G12. Prevention of Accidental Release: Risk Management Plan Notification and Compliance Certification

If the permittee is required to develop and register a risk management plan pursuant to section 112(r) of the Act, the permittee shall notify the department of this requirement. The plan shall be filed with all appropriate authorities by the deadline specified by EPA. A certification that this risk management plan is being properly implemented shall be included in the annual compliance certification of this permit. *567 IAC 22.108(6)*

G13. Hazardous Release

The permittee must report any situation involving the actual, imminent, or probable release of a hazardous substance into the atmosphere which, because of the quantity, strength and toxicity of the substance, creates an immediate or potential danger to the public health, safety or to the environment. A verbal report shall be made to the department at (515) 725-8694 and to the local police department or the office of the sheriff of the affected county as soon as possible but not later than six hours after the discovery or onset of the condition. This verbal report must be followed up with a written report as indicated in 567 IAC 131.2(2). *567 IAC Chapter 131-State Only*

G14. Excess Emissions and Excess Emissions Reporting Requirements

1. Excess Emissions. Excess emission during a period of startup, shutdown, or cleaning of control equipment is not a violation of the emission standard if the startup, shutdown or cleaning is accomplished expeditiously and in a manner consistent with good practice for minimizing emissions. Cleaning of control equipment which does not require the shutdown of the process equipment shall be limited to one six-minute period per one-hour period. An incident of excess emission (other than an incident during startup, shutdown or cleaning of control equipment) is a violation. If the owner or operator of a source maintains that the incident of excess emission was due to a malfunction, the owner or operator must show that the conditions which caused the

incident of excess emission were not preventable by reasonable maintenance and control measures. Determination of any subsequent enforcement action will be made following review of this report. If excess emissions are occurring, either the control equipment causing the excess emission shall be repaired in an expeditious manner or the process generating the emissions shall be shutdown within a reasonable period of time. An expeditious manner is the time necessary to determine the cause of the excess emissions and to correct it within a reasonable period of time. A reasonable period of time is eight hours plus the period of time required to shut down the process without damaging the process equipment or control equipment. A variance from this subrule may be available as provided for in Iowa Code section 455B.143. In the case of an electric utility, a reasonable period of time is eight hours plus the period of time until comparable generating capacity is available to meet consumer demand with the affected unit out of service, unless, the director shall, upon investigation, reasonably determine that continued operation constitutes an unjustifiable environmental hazard and issue an order that such operation is not in the public interest and require a process shutdown to commence immediately.

2. Excess Emissions Reporting

a. Initial Reporting of Excess Emissions. An incident of excess emission (other than an incident of excess emission during a period of startup, shutdown, or cleaning) shall be reported to the appropriate field office of the department within eight hours of, or at the start of the first working day following the onset of the incident. The reporting exemption for an incident of excess emission during startup, shutdown or cleaning does not relieve the owner or operator of a source with continuous monitoring equipment of the obligation of submitting reports required in 567-subrule 25.1(6). An initial report of excess emission is not required for a source with operational continuous monitoring equipment (as specified in 567-subrule 25.1(1)) if the incident of excess emission continues for less than 30 minutes and does not exceed the applicable emission standard by more than 10 percent or the applicable visible emission standard by more than 10 percent opacity. The initial report may be made by electronic mail (E-mail), in person, or by telephone and shall include as a minimum the following:

- i. The identity of the equipment or source operation from which the excess emission originated and the associated stack or emission point.
- ii. The estimated quantity of the excess emission.
- iii. The time and expected duration of the excess emission.
- iv. The cause of the excess emission.
- v. The steps being taken to remedy the excess emission.
- vi. The steps being taken to limit the excess emission in the interim period.

b. Written Reporting of Excess Emissions. A written report of an incident of excess emission shall be submitted as a follow-up to all required initial reports to the department within seven days of the onset of the upset condition, and shall include as a minimum the following:

- i. The identity of the equipment or source operation point from which the excess emission originated and the associated stack or emission point.
- ii. The estimated quantity of the excess emission.
- iii. The time and duration of the excess emission.
- iv. The cause of the excess emission.
- v. The steps that were taken to remedy and to prevent the recurrence of the incident of excess emission.

- vi. The steps that were taken to limit the excess emission.
- vii. If the owner claims that the excess emission was due to malfunction, documentation to support this claim. *567 IAC 24.1(1)-567 IAC 24.1(4)*

3. Emergency Defense for Excess Emissions. For the purposes of this permit, an “emergency” means any situation arising from sudden and reasonably unforeseeable events beyond the control of the source, including acts of God, which situation requires immediate corrective action to restore normal operation, and that causes the source to exceed a technology-based emission limitation under the permit due to unavoidable increases in emissions attributable to the emergency. An emergency shall not include non-compliance, to the extent caused by improperly designed equipment, lack of preventive maintenance, careless or improper operation or operator error. An emergency constitutes an affirmative defense to an action brought for non-compliance with technology based limitations if it can be demonstrated through properly signed contemporaneous operating logs or other relevant evidence that:

- a. An emergency occurred and that the permittee can identify the cause(s) of the emergency;
- b. The facility at the time was being properly operated;
- c. During the period of the emergency, the permittee took all reasonable steps to minimize levels of emissions that exceeded the emissions standards or other requirements of the permit; and
- d. The permittee submitted notice of the emergency to the director by certified mail within two working days of the time when the emissions limitations were exceeded due to the emergency. This notice fulfills the requirement of paragraph 22.108(5)"b." – See G15. This notice must contain a description of the emergency, any steps taken to mitigate emissions, and corrective actions taken.

In any enforcement proceeding, the permittee seeking to establish the occurrence of an emergency has the burden of proof. This provision is in addition to any emergency or upset provision contained in any applicable requirement. *567 IAC 22.108(16)*

G15. Permit Deviation Reporting Requirements

A deviation is any failure to meet a term, condition or applicable requirement in the permit. Reporting requirements for deviations that result in a hazardous release or excess emissions have been indicated above (see G13 and G14). Unless more frequent deviation reporting is specified in the permit, any other deviation shall be documented in the semi-annual monitoring report and the annual compliance certification (see G4 and G5). *567 IAC 22.108(5)"b"*

G16. Notification Requirements for Sources That Become Subject to NSPS and NESHAP Regulations

During the term of this permit, the permittee must notify the department of any source that becomes subject to a standard or other requirement under 567-subrule 23.1(2) (standards of performance of new stationary sources) or section 111 of the Act; or 567-subrule 23.1(3) (emissions standards for hazardous air pollutants), 567-subrule 23.1(4) (emission standards for hazardous air pollutants for source categories) or section 112 of the Act. This notification shall be submitted in writing to the department pursuant to the notification requirements in 40 CFR Section 60.7, 40 CFR Section 61.07, and/or 40 CFR Section 63.9. *567 IAC 23.1(2), 567 IAC 23.1(3), 567 IAC 23.1(4)*

G17. Requirements for Making Changes to Emission Sources That Do Not Require Title V Permit Modification

1. Off Permit Changes to a Source. Pursuant to section 502(b)(10) of the CAAA, the permittee may make changes to this installation/facility without revising this permit if:
 - a. The changes are not major modifications under any provision of any program required by section 110 of the Act, modifications under section 111 of the act, modifications under section 112 of the act, or major modifications as defined in 567 IAC Chapter 22.
 - b. The changes do not exceed the emissions allowable under the permit (whether expressed therein as a rate of emissions or in terms of total emissions);
 - c. The changes are not modifications under any provisions of Title I of the Act and the changes do not exceed the emissions allowable under the permit (whether expressed therein as a rate of emissions or as total emissions);
 - d. The changes are not subject to any requirement under Title IV of the Act (revisions affecting Title IV permitting are addressed in rules 567—22.140(455B) through 567 - 22.144(455B));.
 - e. The changes comply with all applicable requirements.
 - f. For each such change, the permitted source provides to the department and the administrator by certified mail, at least 30 days in advance of the proposed change, a written notification, including the following, which must be attached to the permit by the source, the department and the administrator:
 - i. A brief description of the change within the permitted facility,
 - ii. The date on which the change will occur,
 - iii. Any change in emission as a result of that change,
 - iv. The pollutants emitted subject to the emissions trade
 - v. If the emissions trading provisions of the state implementation plan are invoked, then Title V permit requirements with which the source shall comply; a description of how the emissions increases and decreases will comply with the terms and conditions of the Title V permit.
 - vi. A description of the trading of emissions increases and decreases for the purpose of complying with a federally enforceable emissions cap as specified in and in compliance with the Title V permit; and
 - vii. Any permit term or condition no longer applicable as a result of the change.
2. Such changes do not include changes that would violate applicable requirements or contravene federally enforceable permit terms and conditions that are monitoring (including test methods), record keeping, reporting, or compliance certification requirements. *567 IAC 22.110(2)*
3. Notwithstanding any other part of this rule, the director may, upon review of a notice, require a stationary source to apply for a Title V permit if the change does not meet the requirements of subrule 22.110(1). *567 IAC 22.110(3)*
4. The permit shield provided in subrule 22.108(18) shall not apply to any change made pursuant to this rule. Compliance with the permit requirements that the source will meet using the emissions trade shall be determined according to requirements of the state implementation plan authorizing the emissions trade. *567 IAC 22.110(4)*
5. No permit revision shall be required, under any approved economic incentives, marketable permits, emissions trading and other similar programs or processes, for changes that are provided for in this permit. *567 IAC 22.108(11)*

G18. Duty to Modify a Title V Permit

1. Administrative Amendment.

- a. An administrative permit amendment is a permit revision that does any of the following:
 - i. Correct typographical errors
 - ii. Identify a change in the name, address, or telephone number of any person identified in the permit, or provides a similar minor administrative change at the source;
 - iii. Require more frequent monitoring or reporting by the permittee; or
 - iv. Allow for a change in ownership or operational control of a source where the director determines that no other change in the permit is necessary, provided that a written agreement containing a specific date for transfer of permit responsibility, coverage and liability between the current and new permittee has been submitted to the director.
- b. The permittee may implement the changes addressed in the request for an administrative amendment immediately upon submittal of the request. The request shall be submitted to the director.
- c. Administrative amendments to portions of permits containing provisions pursuant to Title IV of the Act shall be governed by regulations promulgated by the administrator under Title IV of the Act.

2. Minor Title V Permit Modification.

- a. Minor Title V permit modification procedures may be used only for those permit modifications that satisfy all of the following:
 - i. Do not violate any applicable requirement;
 - ii. Do not involve significant changes to existing monitoring, reporting or recordkeeping requirements in the Title V permit;
 - iii. Do not require or change a case by case determination of an emission limitation or other standard, or an increment analysis;
 - iv. Do not seek to establish or change a permit term or condition for which there is no corresponding underlying applicable requirement and that the source has assumed in order to avoid an applicable requirement to which the source would otherwise be subject. Such terms and conditions include any federally enforceable emissions caps which the source would assume to avoid classification as a modification under any provision under Title I of the Act; and an alternative emissions limit approved pursuant to regulations promulgated under section 112(i)(5) of the Act;
 - v. Are not modifications under any provision of Title I of the Act; and
 - vi. Are not required to be processed as significant modification under rule 567 - 22.113(455B).
- b. An application for minor permit revision shall be on the minor Title V modification application form and shall include at least the following:
 - i. A description of the change, the emissions resulting from the change, and any new applicable requirements that will apply if the change occurs;
 - ii. The permittee's suggested draft permit;
 - iii. Certification by a responsible official, pursuant to 567 IAC 22.107(4), that the proposed modification meets the criteria for use of minor permit modification

procedures and a request that such procedures be used; and
iv. Completed forms to enable the department to notify the administrator and the affected states as required by 567 IAC 22.107(7).

c. The permittee may make the change proposed in its minor permit modification application immediately after it files the application. After the permittee makes this change and until the director takes any of the actions specified in 567 IAC 22.112(4) "a" to "c", the permittee must comply with both the applicable requirements governing the change and the proposed permit terms and conditions. During this time, the permittee need not comply with the existing permit terms and conditions it seeks to modify. However, if the permittee fails to comply with its proposed permit terms and conditions during this time period, the existing permit terms and conditions it seeks to modify may be enforced against the facility.

3. Significant Title V Permit Modification.

Significant Title V modification procedures shall be used for applications requesting Title V permit modifications that do not qualify as minor Title V modifications or as administrative amendments. These include but are not limited to all significant changes in monitoring permit terms, every relaxation of reporting or recordkeeping permit terms, and any change in the method of measuring compliance with existing requirements. Significant Title V modifications shall meet all requirements of 567 IAC Chapter 22, including those for applications, public participation, review by affected states, and review by the administrator, as those requirements that apply to Title V issuance and renewal.

The permittee shall submit an application for a significant permit modification not later than three months after commencing operation of the changed source unless the existing Title V permit would prohibit such construction or change in operation, in which event the operation of the changed source may not commence until the department revises the permit. 567 IAC 22.111-567 IAC 22.113

G19. Duty to Obtain Construction Permits

Unless exempted in 567 IAC 22.1(2) or to meet the parameters established in 567 IAC 22.1(1)"c", the permittee shall not construct, install, reconstruct or alter any equipment, control equipment or anaerobic lagoon without first obtaining a construction permit, or conditional permit, or permit pursuant to rule 567 IAC 22.8, or permits required pursuant to rules 567 IAC 22.4, 567 IAC 22.5, 567 IAC 31.3, and 567 IAC 33.3 as required in 567 IAC 22.1(1). A permit shall be obtained prior to the initiation of construction, installation or alteration of any portion of the stationary source or anaerobic lagoon. *567 IAC 22.1(1)*

G20. Asbestos

The permittee shall comply with 567 IAC 23.1(3)"a", and 567 IAC 23.2(3)"g" when activities involve asbestos mills, surfacing of roadways, manufacturing operations, fabricating, insulating, waste disposal, spraying applications, demolition and renovation operations (*567 IAC 23.1(3)"a"*); training fires and controlled burning of a demolished building (*567 IAC 23.2*).

G21. Open Burning

The permittee is prohibited from conducting open burning, except as provided in 567 IAC 23.2. *567 IAC 23.2 except 23.2(3)"j"; 567 IAC 23.2(3)"j" - State Only*

G22. Acid Rain (Title IV) Emissions Allowances

The permittee shall not exceed any allowances that it holds under Title IV of the Act or the regulations promulgated there under. Annual emissions of sulfur dioxide in excess of the number of allowances to emit sulfur dioxide held by the owners and operators of the unit or the designated representative of the owners and operators is prohibited. Exceedences of applicable emission rates are prohibited. "Held" in this context refers to both those allowances assigned to the owners and operators by USEPA, and those allowances supplementally acquired by the owners and operators. The use of any allowance prior to the year for which it was allocated is prohibited. Contravention of any other provision of the permit is prohibited. *567 IAC 22.108(7)*

G23. Stratospheric Ozone and Climate Protection (Title VI) Requirements

1. The permittee shall comply with the standards for labeling of products using ozone-depleting substances pursuant to 40 CFR Part 82, Subpart E:

- a. All containers in which a class I or class II substance is stored or transported, all products containing a class I substance, and all products directly manufactured with a class I substance must bear the required warning statement if it is being introduced into interstate commerce pursuant to § 82.106.
- b. The placement of the required warning statement must comply with the requirements pursuant to § 82.108.
- c. The form of the label bearing the required warning statement must comply with the requirements pursuant to § 82.110.
- d. No person may modify, remove, or interfere with the required warning statement except as described in § 82.112.

2. The permittee shall comply with the standards for recycling and emissions reduction pursuant to 40 CFR Part 82, Subpart F, except as provided for MVACs in Subpart B:

- a. Persons opening appliances for maintenance, service, repair, or disposal must comply with the required practices pursuant to § 82.156.
- b. Equipment used during the maintenance, service, repair, or disposal of appliances must comply with the standards for recycling and recovery equipment pursuant to § 82.158.
- c. Persons performing maintenance, service, repair, or disposal of appliances must be certified by an approved technician certification program pursuant to § 82.161.

- d. Persons disposing of small appliances, MVACs, and MVAC-like appliances must comply with reporting and recordkeeping requirements pursuant to § 82.166. ("MVAC-like appliance" as defined at § 82.152)
 - e. Persons owning commercial or industrial process refrigeration equipment must comply with the leak repair requirements pursuant to § 82.156.
 - f. Owners/operators of appliances normally containing 50 or more pounds of refrigerant must keep records of refrigerant purchased and added to such appliances pursuant to § 82.166.
3. If the permittee manufactures, transforms, imports, or exports a class I or class II substance, the permittee is subject to all the requirements as specified in 40 CFR part 82, Subpart A, Production and Consumption Controls.
 4. If the permittee performs a service on motor (fleet) vehicles when this service involves ozone-depleting substance refrigerant (or regulated substitute substance) in the motor vehicle air conditioner (MVAC), the permittee is subject to all the applicable requirements as specified in 40 CFR part 82, Subpart B, Servicing of Motor Vehicle Air Conditioners. The term "motor vehicle" as used in Subpart B does not include a vehicle in which final assembly of the vehicle has not been completed. The term "MVAC" as used in Subpart B does not include the air-tight sealed refrigeration system used as refrigerated cargo, or system used on passenger buses using HCFC-22 refrigerant,
 5. The permittee shall be allowed to switch from any ozone-depleting or greenhouse gas generating substances to any alternative that is listed in the Significant New Alternatives Program (SNAP) promulgated pursuant to 40 CFR part 82, Subpart G, Significant New Alternatives Policy Program. *40 CFR part 82*

G24. Permit Reopenings

1. This permit may be modified, revoked, reopened, and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any Construction Permit Condition. *567 IAC 22.108(9)"c"*
2. Additional applicable requirements under the Act become applicable to a major part 70 source with a remaining permit term of 3 or more years. Revisions shall be made as expeditiously as practicable, but not later than 18 months after the promulgation of such standards and regulations.
 - a. Reopening and revision on this ground is not required if the permit has a remaining term of less than three years;
 - b. Reopening and revision on this ground is not required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and conditions have been extended pursuant to 40 CFR 70.4(b)(10)(i) or (ii) as amended to May 15, 2001.
 - c. Reopening and revision on this ground is not required if the additional applicable requirements are implemented in a general permit that is applicable to the source and the source receives approval for coverage under that general permit. *567 IAC 22.108(17)"a", 567 IAC 22.108(17)"b"*
3. A permit shall be reopened and revised under any of the following circumstances:
 - a. The department receives notice that the administrator has granted a petition for disapproval of a permit pursuant to 40 CFR 70.8(d) as amended to July 21, 1992, provided that the reopening may be stayed pending judicial review of that determination;

- b. The department or the administrator determines that the Title V permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of the Title V permit;
- c. Additional applicable requirements under the Act become applicable to a Title V source, provided that the reopening on this ground is not required if the permit has a remaining term of less than three years, the effective date of the requirement is later than the date on which the permit is due to expire, or the additional applicable requirements are implemented in a general permit that is applicable to the source and the source receives approval for coverage under that general permit. Such a reopening shall be complete not later than 18 months after promulgation of the applicable requirement.
- d. Additional requirements, including excess emissions requirements, become applicable to a Title IV affected source under the acid rain program. Upon approval by the administrator, excess emissions offset plans shall be deemed to be incorporated into the permit.
- e. The department or the administrator determines that the permit must be revised or revoked to ensure compliance by the source with the applicable requirements. *567 IAC 22.114(1)*

4. Proceedings to reopen and reissue a Title V permit shall follow the procedures applicable to initial permit issuance and shall effect only those parts of the permit for which cause to reopen exists. *567 IAC 22.114(2)*

5. A notice of intent shall be provided to the Title V source at least 30 days in advance of the date the permit is to be reopened, except that the director may provide a shorter time period in the case of an emergency. *567 IAC 22.114(3)*

G25. Permit Shield

1. The director may expressly include in a Title V permit a provision stating that compliance with the conditions of the permit shall be deemed compliance with any applicable requirements as of the date of permit issuance, provided that:

- a. Such applicable requirements are included and are specifically identified in the permit; or
- b. The director, in acting on the permit application or revision, determines in writing that other requirements specifically identified are not applicable to the source, and the permit includes the determination or a concise summary thereof.

2. A Title V permit that does not expressly state that a permit shield exists shall be presumed not to provide such a shield.

3. A permit shield shall not alter or affect the following:

- a. The provisions of Section 303 of the Act (emergency orders), including the authority of the administrator under that section;
- b. The liability of an owner or operator of a source for any violation of applicable requirements prior to or at the time of permit issuance;
- c. The applicable requirements of the acid rain program, consistent with Section 408(a) of the Act;
- d. The ability of the department or the administrator to obtain information from the facility pursuant to Section 114 of the Act. *567 IAC 22.108 (18)*

G26. Severability

The provisions of this permit are severable and if any provision or application of any provision is found to be invalid by this department or a court of law, the application of such provision to

other circumstances, and the remainder of this permit, shall not be affected by such finding. 567 IAC 22.108 (8)

G27. Property Rights

The permit does not convey any property rights of any sort, or any exclusive privilege. 567 IAC 22.108 (9)"d"

G28. Transferability

This permit is not transferable from one source to another. If title to the facility or any part of it is transferred, an administrative amendment to the permit must be sought consistent with the requirements of 567 IAC 22.111(1). 567 IAC 22.111 (1)"d"

G29. Disclaimer

No review has been undertaken on the engineering aspects of the equipment or control equipment other than the potential of that equipment for reducing air contaminant emissions.
567 IAC 22.3(3)"c"

G30. Notification and Reporting Requirements for Stack Tests or Monitor Certification

The permittee shall notify the department's stack test contact in writing not less than 30 days before a required test or performance evaluation of a continuous emission monitor is performed to determine compliance with applicable requirements of 567 – Chapter 23 or a Construction Permit Condition. Such notice shall include the time, the place, the name of the person who will conduct the test and other information as required by the department. If the owner or operator does not provide timely notice to the department, the department shall not consider the test results or performance evaluation results to be a valid demonstration of compliance with applicable rules or Construction Permit Conditions. Upon written request, the department may allow a notification period of less than 30 days. At the department's request, a pretest meeting shall be held not later than 15 days prior to conducting the compliance demonstration. A testing protocol shall be submitted to the department no later than 15 days before the owner or operator conducts the compliance demonstration. A representative of the department shall be permitted to witness the tests. Results of the tests shall be submitted in writing to the department's stack test contact in the form of a comprehensive report within six weeks of the completion of the testing. Compliance tests conducted pursuant to this permit shall be conducted with the source operating in a normal manner at its maximum continuous output as rated by the equipment manufacturer, or the rate specified by the owner as the maximum production rate at which the source shall be operated. In cases where compliance is to be demonstrated at less than the maximum continuous output as rated by the equipment manufacturer, and it is the owner's intent to limit the capacity to that rating, the owner may submit evidence to the department that the source has been physically altered so that capacity cannot be exceeded, or the department may require additional testing, continuous monitoring, reports of operating levels, or any other information deemed necessary by the department to determine whether such source is in compliance.

Stack test notifications, reports and correspondence shall be sent to:

Stack Test Review Coordinator
Iowa DNR, Air Quality Bureau
Wallace State Office Building
502 E 9th St.
Des Moines, IA 50319-0034
(515) 725-9545

Within Polk and Linn Counties, stack test notifications, reports and correspondence shall also be directed to the supervisor of the respective county air pollution program.

567 IAC 25.1(7)"a", 567 IAC 25.1(9)

G31. Prevention of Air Pollution Emergency Episodes

The permittee shall comply with the provisions of 567 IAC Chapter 26 in the prevention of excessive build-up of air contaminants during air pollution episodes, thereby preventing the occurrence of an emergency due to the effects of these contaminants on the health of persons.

567 IAC 26.1(1)

G32. Contacts List

The current address and phone number for reports and notifications to the EPA administrator is:

Iowa Compliance Officer
Air Branch
Enforcement and Compliance Assurance Division
U.S. EPA Region 7
11201 Renner Blvd.
Lenexa, KS 66219
(913) 551-7020

The current address and phone number for reports and notifications to the department or the Director is:

Chief, Air Quality Bureau
Iowa Department of Natural Resources
Wallace State Office Building
502 E 9th St.
Des Moines, IA 50319-0034
(515) 725-8200

Reports or notifications to the DNR Field Offices or local programs shall be directed to the supervisor at the appropriate field office or local program. Current addresses and phone numbers are:

Field Office 1

1101 Commercial Court, Suite 10
Manchester, IA 52057
(563) 927-2640

Field Office 2

2300-15th St., SW
Mason City, IA 50401
(641) 424-4073

Field Office 3

1900 N. Grand Ave.
Spencer, IA 51301
(712) 262-4177

Field Office 4

1401 Sunnyside Lane
Atlantic, IA 50022
(712) 243-1934

Field Office 5

Wallace State Office Building
502 E 9th St.
Des Moines, IA 50319-0034
(515) 725-0268

Field Office 6

1023 West Madison Street
Washington, IA 52353-1623
(319) 653-2135

Polk County Public Works Dept.

Air Quality Division
5885 NE 14th St.
Des Moines, IA 50313
(515) 286-3351

Linn County Public Health

Air Quality Branch
1020 6th Street SE
Cedar Rapids, IA 52401
(319) 892-6000

V. Appendix A: Equipment List

Pharma I Production (EP 303)

Emission Unit Description	EU ID	Maximum Rated Capacity
Centrifuge	C-3709	0.41 m ²
Column	EV-3714-C-1401	20 gallons
Dryer	D-3220	230 ft ³
Dryer	D-3790	7.1 ft ³
Evaporator	EV-3714	1 ft ²
Filter	F-3123	425 L
Filter	F-3140	7 m ²
Filter	F-3168	6 m ²
Filter	F-3708	35.2 gallons
Reactor	R-3142	2,000 gallons
Reactor	R-3144	2,000 gallons
Reactor	R-3146	2,000 gallons
Reactor	R-3148	3,000 gallons
Reactor	R-3149	3,000 gallons
Reactor	R-3150	4,000 gallons
Reactor	R-3160	2,500 gallons
Reactor	R-3162	2,500 gallons
Reactor	R-3166	4,000 gallons
Reactor	R-3178	1,000 gallons
Reactor	R-3601	4,000 gallons
Reactor	R-3603	4,000 gallons
Reactor	R-3701	500 gallons
Reactor	R-3702	500 gallons
Reactor	R-3703	500 gallons
Tank	C-3709-T-0912	50 gallons
Reactor	R-3164	4000 gallons
Tank	H-5002-T-3151	1,030 gallons
Tank	H-6402-T-3147	689 gallons
Tank	R-3701-T-0103	10 gallons
Tank	R-3702-T-0203	10 gallons
Tank	R-3703-T-0303	10 gallons
Tank	T-1216	15,000 gallons
Tank	T-1217	15,000 gallons
Tank	T-1219	12,900 gallons
Tank	T-1232	20,000 gallons
Tank	T-1233	10,000 gallons
Tank	T-1243	15,000 gallons
Tank	T-1244	15,000 gallons
Tank	T-3104	4,000 gallons

Emission Unit Description	EU ID	Maximum Rated Capacity
Tank	T-3110	2,000 gallons
Tank	T-3111	600 gallons
Tank	T-3132	7,500 gallons
Tank	T-3133	7,500 gallons
Tank	T-3134	7,500 gallons
Tank	T-3135	7,500 gallons
Tank	T-3136	7,500 gallons
Tank	T-3137	7,500 gallons
Tank	T-3138	7,500 gallons
Tank	T-3139	5,000 gallons
Tank	T-3141	150 gallons
Tank	T-3152	100 gallons
Tank	T-3163	300 gallons
Tank	T-3176	500 gallons
Tank	T-3177	500 gallons
Tank	T-3179	750 gallons
Tank	T-3180	750 gallons
Reactor - stainless steel	R-3186	1,000 gallons
Tank - glass lined horizontal tank	T-3143	2,000 gallons
Tank - glass lined receiver	T-6471	500 gallons
Tank - glass lined receiver	T-4271	500 gallons
Tank – stainless steel receiver	T-6207	300 gallons
Tank	T-3191	500 gallons
Tank	T-3192	2 gallons
Tank	T-3221	275 gallons
Tank	T-3602	500 gallons
Tank	T-3704	100 gallons
Tank	T-3705	300 gallons
Tank	T-3722	1,500 gallons
Tank	T-3712	40 gallons
Tank	T-3713	40 gallons
Tank	T-3715	40 gallons
Tank	T-5402	50 gallons
Tank	T-5502	50 gallons
Tank	VP-3153-T-5320	30 gallons
Tank	VP-3225-T-2501	20 gallons
Tank	VP-3710-T-1002	75 gallons
Tank	VS-3760-T-6020	700 gallons
Vacuum Pump System	VP-3153	225 ft ³ /min
Vacuum Pump System	VP-3225	200 ft ³ /min
Vacuum Pump System	VP-3710	190 ft ³ /min

Equipment in this facility is grouped into work centers. Work center designations are identified by the first two digits of the EU ID number.

Equipment in Work Center 12, 31, 32, 36 and 37 may use any number of the following control equipment prior to exhausting to the Pharma 1 Main Scrubber under normal operating conditions.

- Three (3) EST Venturi Scrubbers (C-3111, C-3602, C-6020)
- Condenser (including Pfaudler Condenser, model 08-090-BEM)
- Vapor Phase Carbon Adsorption Unit (C-3106)
- Vapor Condensers (H-3110A, H-3110B)
- Venturi scrubber (C-3118)

Equipment in Partially Soluble Hazardous Air Pollutant(s) (PSHAP) service may exhaust through the carbon adsorption unit, C-3106, or the vapor condensers H-3110A or H-3110B, then to the Pharma 1 Main Scrubber. PSHAP is defined in §63.1251 Subpart GGG.

Pharma 1 Production Facility Units Connected to the Flame Arrestor (EP 309)

EU ID	Description	Maximum Capacity
R-3701	Reactor	500 gallons
R-3702	Reactor	500 gallons
R-3703	Reactor	500 gallons
R-3701-T-0103	Tank	10 gallons
R-3702-T-0203	Tank	10 gallons
R-3703-T-0303	Tank	10 gallons
T-3704	Tank	100 gallons
T-3705	Tank	300 gallons
T-3712	Tank	40 gallons
T-3713	Tank	40 gallons
T-3715	Tank	300 gallons

VI. Appendix B: Links to Standards

40 CFR 60 Subpart A – General Provisions

https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40cfr60_main_02.tpl

40 CFR 60 Subpart Kb - Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984

https://www.ecfr.gov/cgi-bin/text-idx?node=sp40.7.60.k_0b

40 CFR 63 Subpart A – General Provisions

https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40cfr63_main_02.tpl

40 CFR 63 Subpart VVVVVV - National Emission Standards for Hazardous Air Pollutants for Chemical Manufacturing Area Sources

<https://www.ecfr.gov/cgi-bin/text-idx?node=sp40.15.63.vvvvvv>

40 CFR 61 Subpart M – National Emission Standards for Asbestos

[https://www.ecfr.gov/cgi-bin/text-](https://www.ecfr.gov/cgi-bin/text-idx?SID=d06e8bb314ba2eb6f3669fc3016acb0e&mc=true&node=sp40.10.61.m&rgn=div6)

[idx?SID=d06e8bb314ba2eb6f3669fc3016acb0e&mc=true&node=sp40.10.61.m&rgn=div6](https://www.ecfr.gov/cgi-bin/text-idx?SID=d06e8bb314ba2eb6f3669fc3016acb0e&mc=true&node=sp40.10.61.m&rgn=div6)

Facility is subject only to the Subpart M NESHAP for the demolition and renovation of asbestos containing structures identified in 40 CFR 61.145.