



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
AIR QUALITY PROGRAM

PLAN APPROVAL

Issue Date: August 17, 2026

Effective Date: August 17, 2026

Expiration Date: February 17, 2028

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

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

Plan Approval No. 46-0005BD

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

Owner Information

Name: MERCK SHARP & DOHME LLC
Mailing Address: 770 SUMNEYTOWN PIKE
PO BOX 4, WP B39-308
WEST POINT, PA 19486-8000

Plant Information

Plant: MERCK SHARP & DOHME LLC/WEST PT
Location: 46 Montgomery County 46953 Upper Gwynedd Township
SIC Code: 2834 Manufacturing - Pharmaceutical Preparations

Responsible Official

Name: DARREN O'TOOLE
Title: AVP, GWES PA OPER.
Phone: (267) 245 - 2243 Email: darren_otool@merck.com

Plan Approval Contact Person

Name: MIKE LORENZ
Title: DIR WP SAFETY & ENV
Phone: (215) 652 - 4955 Email: mike_lorenz@merck.com

[Signature] _____
JILLIAN A. GALLAGHER, SOUTHEAST REGION AIR PROGRAM MANAGER



Plan Approval Description

This plan approval is for the following:

- (a) Construction of a new building, Bldg. 71, with good manufacturing practice (GMP) space, two (2) shell freezers, and construction of a 500-kilowatt (kW) natural gas-fired emergency generator;
- (b) Decommissioning of Source ID 748 (Bldg. 17-1 NG Peak Gen); and,
- (c) Construction of a new 1-megawatt (MW) natural gas-fired non-emergency generator at Bldg. 17.



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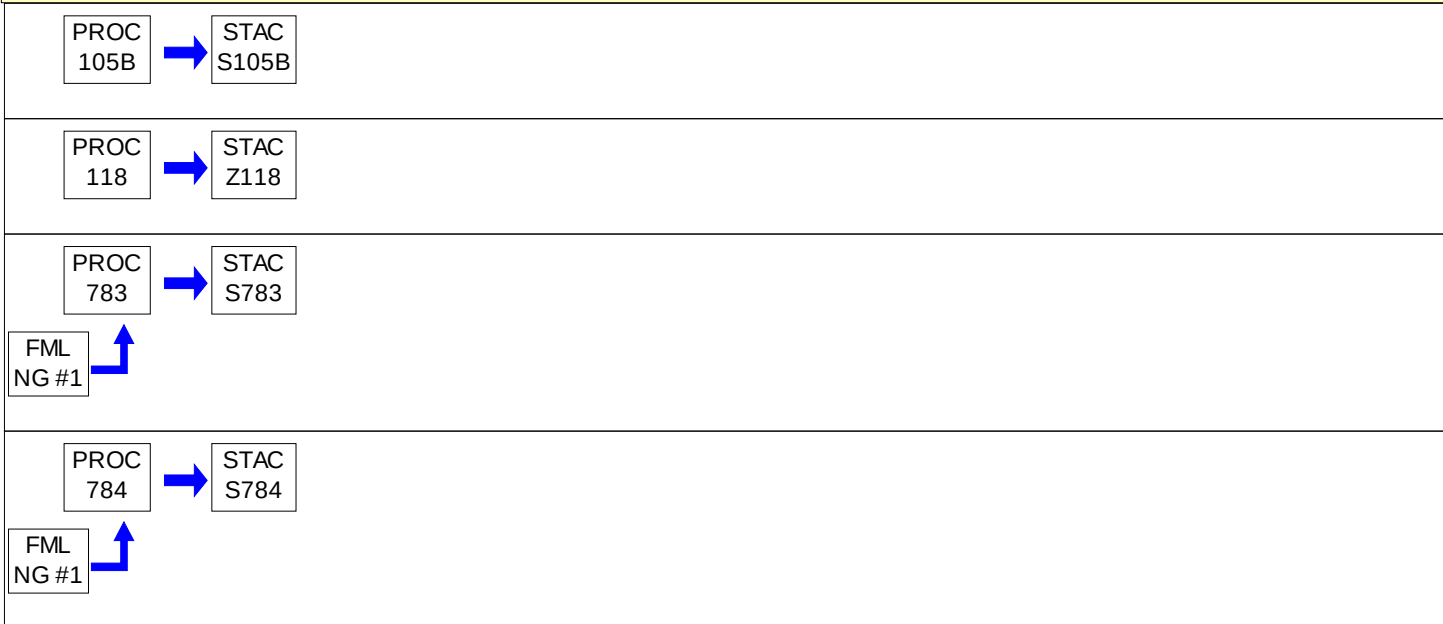
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**SECTION A. Plan Approval Inventory List**

Source ID	Source Name	Capacity/Throughput	Fuel/Material
105B	TWO (2) B71 SHELL FREEZERS	N/A	SOLVENT
118	BLDG 71 GMP SPACE	N/A	SOLVENT
783	BLDG 17-2 NG PEAK GEN	10.980 MCF/HR	Natural Gas
784	BLDG 71-3 NG EMERG GENERATOR	5.820 MCF/HR	Natural Gas
NG #1	NATURAL GAS LINE		
S105B	STACK EMISSIONS - B71 SHELL FREEZERS		
S783	BLDG 17-2 NG PEAK GEN STACK		
S784	BLDG 71-3 NG EMERG GENERATOR STACK		
Z118	BLDG 71 GMP SPACE - FUGITIVES		

PERMIT MAPS

**SECTION B. General Plan Approval Requirements****#001 [25 Pa. Code § 121.1]****Definitions**

Words and terms that are not otherwise defined in this plan approval shall have the meanings set forth in Section 3 of the Air Pollution Control Act (35 P.S. § 4003) and 25 Pa. Code § 121.1.

#002 [25 Pa. Code § 127.12b (a) (b)]**Future Adoption of Requirements**

The issuance of this plan approval does not prevent the future adoption by the Department of any rules, regulations or standards, or the issuance of orders necessary to comply with the requirements of the Federal Clean Air Act or the Pennsylvania Air Pollution Control Act, or to achieve or maintain ambient air quality standards. The issuance of this plan approval shall not be construed to limit the Department's enforcement authority.

#003 [25 Pa. Code § 127.12b]**Plan Approval Temporary Operation**

This plan approval authorizes temporary operation of the source(s) covered by this plan approval provided the following conditions are met.

(a) When construction, installation, modification, or reactivation is being conducted, the permittee shall provide written notice to the Department of the completion of the activity approved by this plan approval and the permittee's intent to commence operation at least five (5) working days prior to the completion of said activity. The notice shall state when the activity will be completed and when the permittee expects to commence operation. When the activity involves multiple sources on different time schedules, notice is required for the commencement of operation of each source.

(b) Pursuant to 25 Pa. Code § 127.12b (d), temporary operation of the source(s) is authorized to facilitate the shakedown of sources and air cleaning devices, to permit operations pending the issuance of a permit under 25 Pa. Code Chapter 127, Subchapter F (relating to operating permits) or Subchapter G (relating to Title V operating permits) or to permit the evaluation of the air contaminant aspects of the source.

(c) This plan approval authorizes a temporary operation period not to exceed 180 days from the date of commencement of operation, provided the Department receives notice from the permittee pursuant to paragraph (a), above.

(d) The permittee may request an extension of the 180-day shakedown period if further evaluation of the air contamination aspects of the source(s) is necessary. The request for an extension shall be submitted, in writing, to the Department at least 30 days prior to the end of the initial 180-day shakedown period and shall provide a description of the compliance status of the source, a detailed schedule for establishing compliance, and the reasons compliance has not been established. This temporary operation period will be valid for a limited time and may be extended for additional limited periods, each not to exceed 180 days.

(e) The notice submitted by the permittee pursuant to subpart (a) above, prior to the expiration of the plan approval, shall modify the plan approval expiration date on Page 1 of this plan approval. The new plan approval expiration date shall be 180 days from the date of commencement of operation.

#004 [25 Pa. Code § 127.12(a) (10)]**Content of Applications**

The permittee shall maintain and operate the sources and associated air cleaning devices in accordance with good engineering practice as described in the plan approval application submitted to the Department.

#005 [25 Pa. Code §§ 127.12(c) and (d) & 35 P.S. § 4013.2]**Public Records and Confidential Information**

(a) The records, reports or information obtained by the Department or referred to at public hearings shall be available to the public, except as provided in paragraph (b) of this condition.

(b) Upon cause shown by the permittee that the records, reports or information, or a particular portion thereof, but not emission data, to which the Department has access under the act, if made public, would divulge production or sales figures or methods, processes or production unique to that person or would otherwise tend to affect adversely the

**SECTION B. General Plan Approval Requirements**

competitive position of that person by revealing trade secrets, including intellectual property rights, the Department will consider the record, report or information, or particular portion thereof confidential in the administration of the act. The Department will implement this section consistent with sections 112(d) and 114(c) of the Clean Air Act (42 U.S.C.A. § 7412(d) and 7414(c)). Nothing in this section prevents disclosure of the report, record or information to Federal, State or local representatives as necessary for purposes of administration of Federal, State or local air pollution control laws, or when relevant in a proceeding under the act.

#006 [25 Pa. Code § 127.12b]**Plan Approval Terms and Conditions**

[Additional authority for this condition is derived from 25 Pa. Code Section 127.13]

(a) This plan approval will be valid for a limited time, as specified by the expiration date contained on Page 1 of this plan approval. Except as provided in § § 127.11a and 127.215 (relating to reactivation of sources; and reactivation), at the end of the time, if the construction, modification, reactivation or installation has not been completed, a new plan approval application or an extension of the previous approval will be required.

(b) If construction has commenced, but cannot be completed before the expiration of this plan approval, an extension of the plan approval must be obtained to continue construction. To allow adequate time for departmental action, a request for the extension shall be postmarked at least thirty (30) days prior to the expiration date. The request for an extension shall include the following:

- (i) A justification for the extension,
- (ii) A schedule for the completion of the construction

If construction has not commenced before the expiration of this plan approval, then a new plan approval application must be submitted and approval obtained before construction can commence.

(c) If the construction, modification or installation is not commenced within 18 months of the issuance of this plan approval or if there is more than an 18-month lapse in construction, modification or installation, a new plan approval application that meets the requirements of 25 Pa. Code Chapter 127, Subchapter B (related to plan approval requirements), Subchapter D (related to prevention of significant deterioration of air quality), and Subchapter E (related to new source review) shall be submitted. The Department may extend the 18-month period upon a satisfactory showing that an extension is justified.

#007 [25 Pa. Code § 127.32]**Transfer of Plan Approvals**

(a) This plan approval may not be transferred from one person to another except when a change of ownership is demonstrated to the satisfaction of the Department and the Department approves the transfer of the plan approval in writing.

(b) Section 127.12a (relating to compliance review) applies to a request for transfer of a plan approval. A compliance review form shall accompany the request.

(c) This plan approval is valid only for the specific source and the specific location of the source as described in the application.

#008 [25 Pa. Code § 127.12(a)(4) & 35 P.S. § 4008 & § 114 of the CAA]**Inspection and Entry**

(a) Pursuant to 35 P.S. § 4008, no person shall hinder, obstruct, prevent or interfere with the Department or its personnel in the performance of any duty authorized under the Air Pollution Control Act.

(b) The permittee shall also allow the Department to have access at reasonable times to said sources and associated air cleaning devices with such measuring and recording equipment, including equipment recording visual observations, as the Department deems necessary and proper for performing its duties and for the effective enforcement of the Air Pollution Control Act and regulations adopted under the act.

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(c) Nothing in this plan approval condition shall limit the ability of the Environmental Protection Agency to inspect or enter the premises of the permittee in accordance with Section 114 or other applicable provisions of the Clean Air Act.

#009 [25 Pa. Code 127.13a]**Plan Approval Changes for Cause**

This plan approval may be terminated, modified, suspended or revoked and reissued if one or more of the following applies:

- (a) The permittee constructs or operates the source subject to the plan approval in violation of the act, the Clean Air Act, the regulations promulgated under the act or the Clean Air Act, a plan approval or permit or in a manner that causes air pollution.
- (b) The permittee fails to properly or adequately maintain or repair an air pollution control device or equipment attached to or otherwise made a part of the source.
- (c) The permittee fails to submit a report required by this plan approval.
- (d) The Environmental Protection Agency determines that this plan approval is not in compliance with the Clean Air Act or the regulations thereunder.

#010 [25 Pa. Code §§ 121.9 & 127.216]**Circumvention**

- (a) The permittee, or any other person, may not circumvent the new source review requirements of 25 Pa. Code Chapter 127, Subchapter E by causing or allowing a pattern of ownership or development, including the phasing, staging, delaying or engaging in incremental construction, over a geographic area of a facility which, except for the pattern of ownership or development, would otherwise require a permit or submission of a plan approval application.
- (b) No person may permit the use of a device, stack height which exceeds good engineering practice stack height, dispersion technique or other technique which, without resulting in reduction of the total amount of air contaminants emitted, conceals or dilutes an emission of air contaminants which would otherwise be in violation of this plan approval, the Air Pollution Control Act or the regulations promulgated thereunder, except that with prior approval of the Department, the device or technique may be used for control of malodors.

#011 [25 Pa. Code § 127.12c]**Submissions**

Reports, test data, monitoring data, notifications shall be submitted to the:

Regional Air Program Manager
PA Department of Environmental Protection
(At the address given on the plan approval transmittal letter or otherwise notified)

#012 [25 Pa. Code § 127.12(a)(9) & 40 CFR Part 68]**Risk Management**

- (a) If required by Section 112(r) of the Clean Air Act, the permittee shall develop and implement an accidental release program consistent with requirements of the Clean Air Act, 40 CFR Part 68 (relating to chemical accident prevention provisions) and the Federal Chemical Safety Information, Site Security and Fuels Regulatory Relief Act (P.L. 106-40).
- (b) The permittee shall prepare and implement a Risk Management Plan (RMP) which meets the requirements of Section 112(r) of the Clean Air Act, 40 CFR Part 68 and the Federal Chemical Safety Information, Site Security and Fuels Regulatory Relief Act when a regulated substance listed in 40 CFR § 68.130 is present in a process in more than the listed threshold quantity at the facility. The permittee shall submit the RMP to the Environmental Protection Agency according to the following schedule and requirements:
 - (1) The permittee shall submit the first RMP to a central point specified by the Environmental Protection Agency no later than the latest of the following:

**SECTION B. General Plan Approval Requirements**

- (i) Three years after the date on which a regulated substance is first listed under § 68.130; or,
- (ii) The date on which a regulated substance is first present above a threshold quantity in a process.

(2) The permittee shall submit any additional relevant information requested by the Department or the Environmental Protection Agency concerning the RMP and shall make subsequent submissions of RMPs in accordance with 40 CFR § 68.190.

(3) The permittee shall certify that the RMP is accurate and complete in accordance with the requirements of 40 CFR Part 68, including a checklist addressing the required elements of a complete RMP.

(c) As used in this plan approval condition, the term "process" shall be as defined in 40 CFR § 68.3. The term "process" means any activity involving a regulated substance including any use, storage, manufacturing, handling, or on-site movement of such substances or any combination of these activities. For purposes of this definition, any group of vessels that are interconnected, or separate vessels that are located such that a regulated substance could be involved in a potential release, shall be considered a single process.

#013 [25 Pa. Code § 121.7]**Prohibition of Air Pollution**

No person may permit air pollution as that term is defined in the Air Pollution Control Act (35 P.S. §§ 4001-4015).

#014 [25 Pa. Code § 127.25]**Compliance Requirement**

A person may not cause or permit the operation of a source subject to § 127.11 (relating to plan approval requirements), unless the source and air cleaning devices identified in the application for the plan approval and the plan approval issued to the source, are operated and maintained in accordance with specifications in the application and conditions in the plan approval issued by the Department. A person may not cause or permit the operation of an air contamination source subject to this chapter in a manner inconsistent with good operating practices.



SECTION C. Site Level Plan Approval Requirements

I. RESTRICTIONS.

Emission Restriction(s).

001 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

(a) The permittee has elected to restrict the facility's Hazardous Air Pollutants (HAPs), as defined in Section 112b of the Clean Air Act, at the facility to the following, not to exceed in any 12 consecutive month period:

- (1) Any single HAP to less than ten (10) tons; and,
- (2) Total HAPs to less than twenty-five (25) tons.

(b) The facility's site-wide HAP emissions shall be monitored and calculated for individual HAP and total HAP emissions on a monthly basis and on a 12 consecutive month period. The above limits are considered synthetic minor HAP emissions limits for the facility.

(c) The permittee shall notify the Department within thirty (30) days of becoming knowledgeable of exceeding the synthetic minor HAP emission limits indicated in (a), above.

II. TESTING REQUIREMENTS.

No additional testing requirements exist except as provided in other sections of this plan approval including Section B (Plan Approval General Requirements).

III. MONITORING REQUIREMENTS.

002 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

(a) The following information shall be monitored on a monthly basis for use in demonstrating compliance with the site-wide Hazardous Air Pollutant (HAP) emission limits, found in this Section, of this Permit:

(1) For the Biological Manufacturing area (Source #105) and other biological manufacturing sources (Sources #107, 108, 111, 112, 113, 114, 116, 117, 118, and 384), which includes shell freezing (Sources #105A, 105B, and 380), disinfection, and the miscellaneous sources (Source #378) of QC labs and BIO Process vents: - monitor solvent purchases or freezer usage, as described in each of the above listed sources in Section D.

(2) For the Research & Development (R&D) area and the miscellaneous source of Pharmaceutical Testing Lab (Source #378): - monitor the quantity and species of HAP solvent purchases and/or usage.

(3) For the Pharmaceutical Manufacturing area (Pharm), which includes the Waste Alcohol Tanks (Source #749) and the following miscellaneous sources (Source #378), QC Laboratory, material supply sampling, and alcohol tanks: - monitor the number of samples, the number of batches, solvent usage, material usage, or material throughput, as described in each of the above listed sources in Section D, of this permit.

(4) For the Powerhouse area, which includes Boilers #3, 5, 7, 8, and 10 (Sources #033, 035, 041, 042, and 045), two Cogen units (Sources #039 and 043), generators (Sources #150, 152, 153, 381, 732, 733, 734, 735, 736, 737, 738, 745, 746, 747, 748, 751, 753, 754, 755, 756, 758, 759, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 776, 783, and 784), and the refrigerated trailer IC engines (Source #383): - monitor fuel throughput or hours of operation, as described in each of the above listed sources in Section D, of this permit.

(5) For the Maintenance Area, which includes the Paint and Carpentry Shops in Miscellaneous VOC Source (Source #378), and the parts cleaners (Source #752): - monitor solvent usage or purchases, as described in each of the above listed sources in Section D, of this permit.

(6) For diesel tanks (Source #378) and for the Gas Fuel Tank/Pump (Source #385), the permittee shall monitor throughputs.

(7) For the Water Utilities area, which includes the Bldg 81 Godwin pump (Source #750), the portable Godwin pumps (Source #750A), and the Bldg 6 fire pump (Source #777) - monitor the hours of operation, as described in each of the above listed sources in Section D, of this permit.

**SECTION C. Site Level Plan Approval Requirements**

(b) The monitoring required by (a)(1)-(3), above, shall be based upon, but not limited to, the following Department and EPA approved methods:

- (1) Approved test methods;
- (2) Certified product data sheets; and/or
- (3) Formulation data from the manufacturer(s).

(c) Any change in the process specific factors for the sources above will require an operating permit modification.

IV. RECORDKEEPING REQUIREMENTS.

003 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

(a) The following information shall be recorded on a monthly basis for use in demonstrating compliance with the site-wide Hazardous Air Pollutant (HAP) emission limits, found in this Section, of this Permit:

(1) For the Biological Manufacturing area (Source #105) and other biological manufacturing sources (Source 107, 108, 111, 112, 113, 114, 116, 117, 118, and 384), which includes shell freezing (Sources #105A, 105B, and 380), disinfection and the miscellaneous sources (Source #378) of QC labs and BIO Process vents: - HAP emissions shall be calculated using the process specific factors and procedures submitted to the Department on July 17th, 2002, or other Department approved method, and solvent purchases or shell freezer usage, as described in each of the above listed sources in Section D, of this permit.

(2) For the Research & Development (R&D) area and the miscellaneous source of Pharmaceutical Testing Lab (Source #378): - HAP emissions shall be calculated using the quantity and species of HAP solvents purchased and/or used, and an emission factor for lab activities or other future Department approved method.

(3) For the Pharmaceutical Manufacturing area (Pharm), which includes the Waste Alcohol Tanks (Source #749) and the following miscellaneous sources (Source #378): QC Laboratory, material supply sampling, and alcohol tanks: - HAP emissions shall be calculated using the most recent version of the Tank ESP program (or other appropriate program), EmitExcel (or other appropriate program), the number of samples or batches, solvent usage, material usage or throughput with site specific emission factors and procedures as submitted to the Department on July 17th, 2002, or other Department approved method, and as described in each of the above listed sources in Section D, of this permit.

(4) For the Powerhouse area, which includes Boilers #3, 5, 7, 8, and 10 (Sources #033, 035, 041, 042, and 045), two Cogen units (Sources #039 and 043), generators (Sources #150, 152, 153, 381, 732, 733, 734, 735, 736, 737, 738, 745, 746, 747, 748, 751, 753, 754, 755, 756, 758, 759, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 776, 783, and 784), and the refrigerated trailer IC engines (Source #383): - HAP emissions shall be calculated using the source specific emission factors from stack testing, AP-42 emission factors, or EPA revised HAP factors developed for MACT screening along with the monitored fuel throughput or hours of operation, as described in each of the above listed sources in Section D, of this permit.

(5) For the Maintenance Area, which includes the Paint and Carpentry Shops in Miscellaneous VOC Source (Source #378), and the parts cleaners (Source #752): - HAP emissions shall be calculated using a source specific emission factor along with solvent purchases or usage, as described in Section D, of this permit.

(6) For diesel tanks (Source #378) and for the Gas Fuel Tank/Pump (Source #385), the permittee shall record throughputs, and HAP emissions shall be calculated using the TankESP program (or other appropriate program).

(7) For the Water Utilities area, which includes the Bldg 81 Godwin pump (Source #750, the portable Godwin pumps (Source #750A), and the Bldg 6 fire pump (Source #777) - HAP emissions shall be calculated using AP-42 factors along with hours of operation, as described in each of the above listed sources in Section D, of this permit.

(b) The recording required by (a)(1)-(3), above, shall be based upon, but not limited to, the following Department and EPA approved methods:

**SECTION C. Site Level Plan Approval Requirements**

- (1) Approved test methods;
- (2) certified product data sheets; and/or
- (3) formulation data from the manufacturer(s).

(c) Any change in the process specific factors for the sources above will require an operating permit modification.

V. REPORTING REQUIREMENTS.**# 004 [25 Pa. Code §127.12b]****Plan approval terms and conditions.**

(a) The permittee shall report malfunctions, emergencies or incidents of excess emissions to DEP's 24-hour Emergency Hotline at 800.541.2050. A malfunction is any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. An emergency is any situation arising from sudden and reasonably unforeseeable events beyond the control of the owner or operator of a facility which requires immediate corrective action to restore normal operation and which causes the emission source to exceed emissions, due to unavoidable increases in emissions attributable to the situation. An emergency shall not include situations caused by improperly designed equipment, lack of preventive maintenance, careless or improper operation, or operator error.

(b) When the malfunction, emergency or incident of excess emissions poses an imminent danger to the public health, safety, welfare, or environment, it shall be reported to the Department and the County Emergency Management Agency by telephone within one (1) hour after the discovery of the malfunction, emergency or incident of excess emissions. The owner or operator shall electronically submit any report of instances of such malfunctions, emergencies or incidents of excess emissions to the Department within three (3) business days of the telephone report.

(c) The report shall describe the following:

- (1) Name, permit or authorization number, and location of the facility;
- (2) Nature and cause of the malfunction, emergency or incident;
- (3) Date and time when the malfunction, emergency or incident was first observed;
- (4) Expected duration of excess emissions;
- (5) Estimated rate of emissions; and
- (6) Corrective actions or preventative measures taken.

(d) Any malfunction, emergency or incident of excess emissions that is not subject to the notice requirements of paragraph (b) of this condition shall be reported to the Department by telephone within 24 hours (or by 4:00 PM of the next business day, whichever is later) of discovery and in writing or electronically within five (5) business days of discovery. The report shall contain the same information required by paragraph (c), and any permit specific malfunction reporting requirements.

(e) During an emergency an owner or operator may continue to operate the source at their discretion provided they submit justification for continued operation of a source during the emergency and follow all the notification and reporting requirements in accordance with paragraphs (b)-(d), as applicable, including any permit specific malfunction reporting requirements.

(f) Reports regarding malfunctions, emergencies or incidents of excess emissions shall be submitted to the appropriate DEP Regional Office Air Program Manager.

(g) Any emissions resulting from malfunction or emergency are to be reported in the annual emissions inventory report, if the annual emissions inventory report is required by permit or authorization.

VI. WORK PRACTICE REQUIREMENTS.

No additional work practice requirements exist except as provided in other sections of this plan approval including Section B (Plan Approval General Requirements).



SECTION C. Site Level Plan Approval Requirements

VII. ADDITIONAL REQUIREMENTS.

005 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

(a) Per this Plan Approval, the Bldg. 17-1 NG Peak Gen (Source ID 748) shall be shut down and permanently decommissioned.

(b) The permittee shall comply with all the requirements of Section C of Title V Operating Permit No. 46-00005, except as revised herein this Plan Approval.

VIII. COMPLIANCE CERTIFICATION.

No additional compliance certifications exist except as provided in other sections of this plan approval including Section B (relating to Plan Approval General Requirements).

IX. COMPLIANCE SCHEDULE.

No compliance milestones exist.

**SECTION D. Source Level Plan Approval Requirements**

Source ID: 105B

Source Name: TWO (2) B71 SHELL FREEZERS

Source Capacity/Throughput:

N/A

SOLVENT

PROC 105B	➔	STAC S105B
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I. RESTRICTIONS.**Emission Restriction(s).**

001 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

(a) The combined volatile organic compound (VOC) emissions from the two (2) shell freezers shall not exceed 2.49 tons in any 12 consecutive month period.

(b) The combined hazardous air pollutant (HAP) emissions from the two (2) shell freezers shall not exceed 0.12 ton in any 12 consecutive month period.

Control Device Efficiency Restriction(s).

002 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

VOC emissions from the shell freezers shall be controlled by the following:

- (a) Shell freezers are equipped with liquid nitrogen cooling coils; and,
- (b) Access doors fitted with gaskets to seal the vessel.

II. TESTING REQUIREMENTS.

No additional testing requirements exist except as provided in other sections of this plan approval including Section B (Plan Approval General Requirements).

III. MONITORING REQUIREMENTS.

003 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The permittee shall monitor shell freezer usage for shell freezer operations on a monthly basis to assure compliance with the VOC and HAP emission limits applicable to this source.

IV. RECORDKEEPING REQUIREMENTS.

004 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The permittee shall maintain monthly and 12-consecutive month records of VOC and HAP emissions from this source.

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this plan approval including Section B (Plan Approval General Requirements).

VI. WORK PRACTICE REQUIREMENTS.

005 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

- (a) Monthly shell freezer usage records and source-specific emission factors, or, monthly shell freezer usage records and

**SECTION D. Source Level Plan Approval Requirements**

process-specific emission factors shall be used to calculate the VOC emissions for use in demonstrating compliance with the point VOC emission limit for this source.

(b) The parameters used for the source specific emission factors shall be verified once during the life of this operating permit. These shall include, but not be limited to:

- (1) Number of sources;
- (2) Air flow; and
- (3) Seal integrity.

006 [25 Pa. Code §127.12b]**Plan approval terms and conditions.**

Exhaust fans shall pull alcohol vapors from the shell freezer(s) when the access door(s) are open.

007 [25 Pa. Code §127.12b]**Plan approval terms and conditions.**

(a) The permittee shall operate and maintain this source in accordance with good operating and maintenance practices. At a minimum, the following work practices shall be followed:

- (1) Good housekeeping procedures for the storage, use, and disposal of solvents;
- (2) Employee training detailing good work practices to control solvent usage for minimizing emissions;
- (3) Periodic inspection of production and cleaning activities; and
- (4) Solvent containers shall be closed when not in use.

(b) Manufacturer's specifications for maintenance and operation, or records of repair and maintenance shall be made available to the Department upon request.

VII. ADDITIONAL REQUIREMENTS.**# 008 [25 Pa. Code §127.12b]****Plan approval terms and conditions.**

(a) This source consists of two (2) shell freezers that are custom-made tank-like refrigeration units which contain a cooled denature alcohol bath.

(b) The two (2) shell freezers shall be located in Bldg. 71.

**SECTION D. Source Level Plan Approval Requirements**

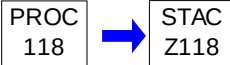
Source ID: 118

Source Name: BLDG 71 GMP SPACE

Source Capacity/Throughput:

N/A

SOLVENT

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

001 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

VOC emissions from the disinfecting operations in Bldg. 71 shall not exceed 2.42 tons in any 12 consecutive month period.

II. TESTING REQUIREMENTS.

No additional testing requirements exist except as provided in other sections of this plan approval including Section B (Plan Approval General Requirements).

III. MONITORING REQUIREMENTS.

002 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

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

IV. RECORDKEEPING REQUIREMENTS.

003 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

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

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

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this plan approval including Section B (Plan Approval General Requirements).

VI. WORK PRACTICE REQUIREMENTS.

004 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

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

005 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

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

- (a) Good housekeeping procedures for the use (dispensing only the amount needed), and disposal of solvents and solvent

**SECTION D. Source Level Plan Approval Requirements**

laden wipes into closed, non-absorbent, and non-leaking containers;

(b) Employee training detailing good work practices to control solvent usage for minimizing emissions;

(c) Periodic inspection of production and cleaning activities;

(d) Ordering cleaners and disinfectants only from company approved vendors; and

(e) Containers with solvent shall be closed or covered when not in use.

VII. ADDITIONAL REQUIREMENTS.

006 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

This source consists of Bldg. 71 area emissions that are generated during aseptic disinfection procedures using a solvent-based solution.

**SECTION D. Source Level Plan Approval Requirements**

Source ID: 783

Source Name: BLDG 17-2 NG PEAK GEN

Source Capacity/Throughput:

10.980 MCF/HR

Natural Gas

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

001 [25 Pa. Code §123.13]

Processes

Particulate matter emissions from this engine shall not exceed 0.04 gr/dscf at any time.

002 [25 Pa. Code §123.21]

GeneralNo person may permit the emission into the outdoor atmosphere of sulfur oxides from this source in a manner that the concentration of the sulfur oxides, expressed as SO₂, in the effluent gas exceeds 500 ppmvd.

003 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4233]

Subpart JJJJ - Standards of Performance for Stationary Spark Ignition Internal Combustion Engines**What emission standards must I meet if I am an owner or operator of a stationary SI internal combustion engine?**

[Additional authority for this permit condition is also derived from 25 Pa. Code § 127.12b]

This engine shall be certified to meet the following emission rates:

- (a) Nitrogen Oxide (NO_x) - 1.0 g/hp-hr;
- (b) Volatile Organic Compounds (VOC) - 0.7 g/hp-hr; and
- (c) Carbon Monoxide (CO) - 2.0 g/hp-hr.

Fuel Restriction(s).

004 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

This engine shall only operate on natural gas.

Operation Hours Restriction(s).

005 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

Operating hours for this engine shall not exceed 150 hours in any 12-consecutive month period.

II. TESTING REQUIREMENTS.

006 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4243]

Subpart JJJJ - Standards of Performance for Stationary Spark Ignition Internal Combustion Engines**What are my compliance requirements if I am an owner or operator of a stationary SI internal combustion engine?**

[Additional authority for this permit condition is also derived from 40 C.F.R. § 60.4245]

- (a) If the permittee does not operate and maintain Source ID 783 according to the manufacturer's emission-related written instructions, the permittee must conduct an initial performance test to demonstrate compliance with the applicable emission limits contained herein this operating permit within 1 year of startup.

**SECTION D. Source Level Plan Approval Requirements**

(b) If performance testing is conducted on Source ID 783, performance testing shall be conducted in accordance with 40 C.F.R. § 60.4244.

(c) If performance testing is conducted on Source ID 783, the permittee must submit a copy of each performance test as conducted in accordance with 40 C.F.R. § 60.4244 within 60 days after the test has been completed.

III. MONITORING REQUIREMENTS.

007 [25 Pa. Code §127.12b]
Plan approval terms and conditions.

The engine associated with Source ID 783 shall be equipped with a non-resettable meter to monitor hours of operation.

IV. RECORDKEEPING REQUIREMENTS.

008 [25 Pa. Code §127.12b]
Plan approval terms and conditions.

The permittee shall record the operating time on a monthly and a 12-consecutive month basis.

009 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4245]
Subpart JJJJ - Standards of Performance for Stationary Spark Ignition Internal Combustion Engines
What are my notification, reporting, and recordkeeping requirements if I am an owner or operator of a stationary SI internal combustion engine?

[Additional authority for this permit condition is also derived from 40 C.F.R. § 60.4243]

(a) The permittee shall keep records of the following information:

- (1) All notifications submitted to comply with 40 C.F.R. Part 60, Subpart JJJJ, and all documentation supporting any notification.
- (2) Maintenance conducted on the engine.
- (3) Documentation that the engine meets the short-term emission limits for NO_x, CO, and VOC.

(b) If the permittee does not operate and maintain Source ID 783 according to the manufacturer's emission-related written instructions, the permittee must keep a maintenance plan and records of conducted maintenance to demonstrate compliance.

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this plan approval including Section B (Plan Approval General Requirements).

VI. WORK PRACTICE REQUIREMENTS.

010 [25 Pa. Code §127.12b]
Plan approval terms and conditions.

[Additional authority for this permit condition is also derived from 40 C.F.R. § 60.4243]

The permittee shall maintain and operate the engine in a manner consistent with good air pollution control practice and in accordance with Merck's generator preventative maintenance program.

VII. ADDITIONAL REQUIREMENTS.

011 [25 Pa. Code §127.12b]
Plan approval terms and conditions.

This source consists of a 4-stroke, lean-burn, natural gas fired Caterpillar engine, Model Number G3512, rated 1,468 bhp.

**SECTION D. Source Level Plan Approval Requirements**

This engine will power a 1,000 kW generator that will be used for non-emergency and peak shaving use for Building 17.

012 [25 Pa. Code §129.203]**Stationary internal combustion engines.**

(a) By October 31 of each year, the permittee shall calculate the difference between the actual emissions from the affected internal combustion engine during the period from May 1 through September 30, and the allowable emissions for that same period.

(b) The allowable emissions shall be calculated by multiplying the cumulative hours or operations for this source for the period by the horsepower rating of the unit and by the applicable emission rate of 3.0 g of NO_x per brake hp-hr.

013 [25 Pa. Code §129.204]**Emission accountability.**

(a) If the affected source has NO_x CEMS, the permittee shall determine actual emissions in accordance with the CEMS data reported to the Department shall be used. Any data invalidated under 25 Pa. Code, Chapter 139 (relating to sampling and testing) shall be substituted with data calculated using the potential emission rate for the unit or, if approved by the Department in writing, an alternative amount of emissions that is more representative of actual emissions that occurred during the period of invalid data.

(b) If the permittee is not required to monitor NO_x emissions with a CEMS, one of the following shall be used to determine actual emissions of NO_x:

(1) The 1-year average emission rate calculated from the most recent permit emission limit compliance demonstration test data for NO_x.

(2) The maximum hourly allowable NO_x emission rate contained in the permit or the higher of the following:

(i) The highest rate determined by use of the emission factor for the unit class contained in the most up-to date version of the EPA publication, "AP-42 Compilation of Air Pollution Emission Factors."

(ii) The highest rate determined by use of the emission factor for the unit class contained in the most up-to date version of EPA's "Factor Information Retrieval (FIRE)" data system.

(3) CEMS data, if the owner or operator elects to monitor NO_x emissions with a CEMS. The owner or operator shall monitor emissions and report the data from the CEMS in accordance with Chapter 139 or Chapter 145 (relating to interstate pollution transport reduction). Any data invalidated under Chapter 139 shall be substituted with data calculated using the potential emission rate for the unit or, if approved by the Department in writing, an alternative amount of emissions that is more representative of actual emissions that occurred during the period of invalid data.

(4) An alternate calculation and recordkeeping procedure based upon emissions testing and correlations with operating parameters. The operator of the unit shall demonstrate that the alternate procedure does not underestimate actual emissions throughout the allowable range of operating conditions. The alternate calculation and recordkeeping procedures must be approved by the Department, in writing, prior to implementation.

014 [25 Pa. Code §129.204]**Emission accountability.**

(a) The permittee shall surrender to the Department one CAIR NO_x allowance and one CAIR NO_x Ozone Season allowance, as defined in 40 C.F.R. § 96.102 and 96.302 (relating to definitions), for each ton of NO_x by which the combined actual emissions exceed the allowable emissions of the units subject to this section at a facility from May 1 through September 30. The surrendered allowances shall be of current year vintage. For the purpose of determining the amount of allowances to surrender, any remaining fraction of a ton equal to or greater than 0.50 ton is deemed to equal 1 ton and any fraction of a ton less than 0.50 ton is deemed to equal zero tons.

(b) If the combined allowable emissions from units subject to 25 Pa. Code § 129.204 at a facility from May 1 through

**SECTION D. Source Level Plan Approval Requirements**

September 30 exceed the combined actual emissions from same units at the facility during the same period, the permittee may deduct the difference or any portion of the difference from the amount of actual emissions from units subject to this section at the permittee's other facilities.

(c) By November 1 of each year, the permittee shall surrender the required NOx allowances to the Department's designated NOx allowance tracking system account and provide to the Department, in writing, the following;

- (1) The serial number of each NOx allowance surrendered.
- (2) The calculations used to determine the quantity of NOx allowances required to be surrendered.

(d) If the permittee fails to comply with (c), above, the permittee shall by December 31 surrender three (3) NOx allowances of the current or later year vintage for each NOx allowance that was required to be surrendered by November 1 of that year.

(e) The surrender of NOx allowances under (d), above, does not affect the liability of the permittee of the unit for any fine, penalty or assessment, or an obligation to comply with any other remedy for the same violation, under the CAA or the act.

- (1) For purposes of determining the number of days of violation, if a facility has excess emissions for the period May 1 through September 30, each day in that period (153 days) constitutes a day in violation unless the permittee demonstrates that a lesser number of days should be considered.
- (2) Each ton of excess emissions is a separate violation.

*CAIR has been replaced by CSAPR. Beginning May 1, 2021, the permittee shall comply with CSAPR rule as promulgated in 40 CFR parts 51, 52, 78 and 97 as published in the Federal Registrar, Vol. 86, No. 82 April 30, 2021.

**SECTION D. Source Level Plan Approval Requirements**

Source ID: 784

Source Name: BLDG 71-3 NG EMERG GENERATOR

Source Capacity/Throughput:

5.820 MCF/HR

Natural Gas

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

001 [25 Pa. Code §123.13]

Processes

Particulate matter emissions from this engine shall not exceed 0.04 gr/dscf at any time.

002 [25 Pa. Code §123.21]

GeneralNo person may permit the emission into the outdoor atmosphere of sulfur oxides from this source in a manner that the concentration of the sulfur oxides, expressed as SO₂, in the effluent gas exceeds 500 ppmvd.

003 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

Emissions from this engine shall not exceed any of the following:

- (a) Nitrogen Oxides (NO_x) - 1.0 grams/hp-hr;
- (b) Carbon Monoxide (CO) - 2.0 grams/hp-hr; and
- (c) Volatile Organic Compounds (VOC) - 0.7 grams/hp-hr.

Fuel Restriction(s).

004 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

This engine shall only operate on natural gas.

Operation Hours Restriction(s).

005 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

Operating hours for this engine shall not exceed 100 hours in any 12-consecutive month period.

II. TESTING REQUIREMENTS.

No additional testing requirements exist except as provided in other sections of this plan approval including Section B (Plan Approval General Requirements).

III. MONITORING REQUIREMENTS.

006 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The permittee shall monitor the operating hours for this engine using a non-resettable meter or Department approved equivalent.



SECTION D. Source Level Plan Approval Requirements

IV. RECORDKEEPING REQUIREMENTS.

007 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The permittee shall record the operating time on a monthly, and a 12-consecutive month, basis.

008 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4245]

Subpart JJJJ - Standards of Performance for Stationary Spark Ignition Internal Combustion Engines

What are my notification, reporting, and recordkeeping requirements if I am an owner or operator of a stationary SI internal combustion engine?

Additional authority for this permit condition is derived from 25 Pa. Code § 127.12b]

The permittee shall retain the following information for a minimum of five (5) years:

- (a) All notifications submitted to comply with 40 CFR 60, Subpart JJJJ and all supporting documentation;
- (b) All maintenance conducted on this engine; and,
- (c) All manufacturer's documentation that this engine is certified to meet the emission standards and information as required in 40 CFR Parts 90, 1048, 1054, and 1060, as applicable.

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this plan approval including Section B (Plan Approval General Requirements).

VI. WORK PRACTICE REQUIREMENTS.

009 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The permittee shall:

- (a) Operate and maintain this engine in accordance with Merck's established generator preventative maintenance program; and,
- (b) Keep records of conducted maintenance.

[Compliance with this condition assures compliance with 40 CFR § 60.4243(a)(1).]

010 [40 CFR Part 60 Standards of Performance for New Stationary Sources §40 CFR 60.4243]

Subpart JJJJ - Standards of Performance for Stationary Spark Ignition Internal Combustion Engines

What are my compliance requirements if I am an owner or operator of a stationary SI internal combustion engine?

[Additional authority for this permit condition is derived from 25 Pa. Code § 127.12b.]

This engine must be operated in accordance with 40 CFR § 60.4243(d). Any subsequent revisions to this federal regulation will automatically supersede this permit condition.

VII. ADDITIONAL REQUIREMENTS.

011 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

- (a) This source consists of an EPA Certified, 760 hp, 4-stroke, lean-burn, natural gas fired Caterpillar engine, Model Number CG18.
- (b) This engine will power a 500 kW emergency generator that will be used to provide back-up electrical power to Building 71.

**SECTION D. Source Level Plan Approval Requirements**

(c) This unit shall not be used for peak shaving purposes or to provide power to the electric grid.



SECTION E. Source Group Plan Approval Restrictions.

**SECTION F. Alternative Operation Requirements.**

No Alternative Operations exist for this Plan Approval facility.

**SECTION G. Emission Restriction Summary.**

Source Id	Source Description
105B	TWO (2) B71 SHELL FREEZERS
Emission Limit	
0.120 Tons/Yr	Determined on a 12-month rolling basis
2.490 Tons/Yr	Determined on a 12-month rolling basis
Pollutant	
Hazardous Air Pollutants	
VOC	
118	BLDG 71 GMP SPACE
Emission Limit	
2.420 Tons/Yr	Determined on a 12-month rolling basis
Pollutant	
VOC	
783	BLDG 17-2 NG PEAK GEN
Emission Limit	
2.000 GRAMS/HP-Hr	
1.000 GRAMS/HP-Hr	
0.040 gr/DRY FT3	
500.000 PPMV	Determined on a dry basis
0.700 GRAMS/HP-Hr	
Pollutant	
CO	
NOX	
PM_FILT	
SOX	
VOC	
784	BLDG 71-3 NG EMERG GENERATOR
Emission Limit	
2.000 GRAMS/HP-Hr	
1.000 GRAMS/HP-Hr	
0.040 gr/DRY FT3	
500.000 PPMV	Determined on a dry basis
0.700 GRAMS/HP-Hr	
Pollutant	
CO	
NOX	
PM_FILT	
SOX	
VOC	

Site Emission Restriction Summary

Emission Limit		Pollutant
10.000 Tons/Yr	Individual HAP; Determined on a 12-month rolling basis	Hazardous Air Pollutants
25.000 Tons/Yr	Total HAP; Determined on a 12-month rolling basis	Hazardous Air Pollutants



SECTION H. Miscellaneous.



***** End of Report *****
