COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF AIR QUALITY

GENERAL PLAN APPROVAL
BAQ-GPA – 24
PHARMACEUTICAL AND SPECIALTY CHEMICAL PRODUCTION

1. Statutory Authority and General Description

In accordance with Section 6.1(f) of the Air Pollution Control Act, 35 P.S. § 4006.1, and 25 Pa. Code §127.622, the Department of Environmental Protection (Department) hereby issues this Pharmaceutical and Specialty Chemical Production General Plan Approval (hereinafter referred to as "Pharm/Chem General Plan Approval").

2. Applicability/Source Coverage Limitations

This Pharm/Chem General Plan Approval is designed to be used as a Plan Approval for regulated facilities that construct sources or modify sources to produce and/or handle pharmaceutical and/or specialty chemical products that result in an increase in emissions of Volatile Organic Compounds (VOCs) and/or Hazardous Air Pollutants (HAPs), the emission of a HAP not previously emitted or a change in HAP emission release characteristics. This Pharm/Chem General Plan Approval does not authorize the installation of new air pollution control devices, except for vent condensers. Use of this Pharm/Chem General Plan Approval is limited to Title V permitted facilities that produce or handle pharmaceutical or specialty chemical products and which have a previously established Plantwide Applicability Limit (PAL) for VOC emissions.

Pharmaceutical and Specialty Chemical Processes, for the purpose of this Pharm/Chem General Plan Approval, are limited to those processes classified under SIC codes 2833 through 2844 and 2879.

Plan Approval

This Pharm/Chem General Plan Approval authorizes the construction of sources and modification of sources that meet the best available technology (BAT) required under 25 Pa. Code §§127.1 and 127.12(a)(5) provided the construction or modification of the source does not cause any exceedance of the site's established VOC PAL emission limitation.

For purposes of this Pharm/Chem General Plan Approval, BAT for a new process shall include the use of existing control devices for control of emissions and compliance with the requirements described in Condition 13 below. A facility owner or operator may use this Pharm/Chem General Plan Approval as a plan approval, and the appropriate provisions of this Pharm/Chem General Plan Approval will then be incorporated into the Title V operating permit as an administrative amendment. If a new or modified process at a facility requires installation of a new air pollution control device, except for a vent condenser, or cannot be regulated by the requirements of the Pharm/Chem General Plan Approval, a plan approval issued in accordance with 25 Pa. Code, Chapter 127, Subchapter B (relating to plan approval requirements) will be required.

Operating Permit

This Pharm/Chem General Plan Approval is not intended for use as an operating permit by a "Title V facility" as defined in 25 Pa. Code §121.1, but rather is intended to be used as an interim operating permit until changes authorized under GPA-24 are incorporated into a Title V permit. This Pharm/Chem General Plan Approval and approved changes shall be incorporated into the facility's Title V permit via an Administrative Amendment including any increase in VOC and/or HAP BAT emission limits as a result of new source construction or modification.

3. Application for Use

Any person seeking coverage under this Pharm/Chem General Plan Approval shall submit an application on a form provided by the Department. The applicant shall not begin construction of sources or the modification of sources for which the application is being made, as required in 25 Pa. Code §127.621 (relating to application for use of general plan approvals and general operating permits), prior to receiving Department approval for use of this Pharm/Chem General Plan Approval. The Department will take action on the application within (30) days of receipt.

4. Compliance

Any facility owner or operator using this Pharm/Chem General Plan Approval must comply with the specifications in the application and the terms and conditions of the Pharm/Chem General Plan Approval. The potential to emit of the Pharm/Chem facility proposing to operate under this General Plan Approval and/or Operating Permit shall be limited by the information provided in the application. Copies of the Pharm/Chem General Plan Approvals and applications shall be maintained at the facility and made available to the Department upon request. The Pharm/Chem facility and any associated air contaminant sources and/or air pollution control devices shall be operated and maintained in a manner consistent with good operating and maintenance practices as required by 25 Pa. Code §§ 127.25 and 127.444 (relating to compliance requirements).

5. Plan Approval Modification, Suspension and Revocation

Coverage under this Pharm/Chem General Plan Approval may be modified and the Department may suspend or revoke the authorization to use this Pharm/Chem General Plan Approval if the Department determines that the affected Pharm/Chem facility cannot be adequately regulated under this Pharm/Chem General Plan Approval. The Department may also suspend or revoke the authorization to temporarily operate under this Pharm/Chem General Plan Approval if the facility owner or operator fails to comply with applicable terms and conditions of the Pharm/Chem General Plan Approval.

6. Notice Requirements

The owner or operator of the facility shall comply with the applicable requirements established in 25 Pa. Code Chapter 127, Subchapter H (relating to general plan approvals and operating permits). The application required by 25 Pa. Code §127.621 shall be sent to the appropriate Regional Office responsible for approval of the use of this Pharm/Chem General Plan Approval in the county in which the Pharm/Chem facility is located.

The owner or operator of the facility shall immediately notify the Department of any malfunction of plant equipment or associated air cleaning device(s), which results in or may result in the emission of air contaminants in excess of any applicable Pharm/Chem General Plan Approval limitation.

a. When the malfunction, excess emissions or deviation from Pharm/Chem General Plan Approval requirements poses an imminent and substantial danger to the public health and safety or the environment, the facility owner or operator shall notify the Department by telephone no later than one (1) hour after the incident.

b. Unless otherwise required by specific reporting requirements, any malfunction, excess emission or deviation from Pharm/Chem General Plan Approval requirements that is not subject to the notice requirements of a. above shall be reported to the Department within one (1) working day of discovery.

7. Definitions

For purposes of this Pharm/Chem General Plan Approval, the following definitions apply:

a. Air Pollution Control Device– Equipment installed that reduces the mass of contaminants emitted to the air from a process vent, storage vessel, wastewater treatment exhaust stack, or

combination thereof. The equipment may consist of an individual device or a series of devices. Examples include but are not limited to, incinerators, carbon adsorption units, condensers, flares, boilers, process heaters, and gas absorbers. Process condensers are not considered air pollution control devices.

b. Batch operation means a noncontinuous operation involving intermittent or discontinuous feed into equipment, and, in general, involves the emptying of the equipment after the batch operation ceases and prior to beginning a new operation. Addition of raw material and withdrawal of product do not occur simultaneously in a batch operation.

c. Combustion Control Device – A control device, other than a flare, such as a Thermal Oxidizing Unit (TOU) or catalytic oxidizer, which is used to oxidize organic vapors.

d. Process – A method, reaction or operation in which materials are handled or whereby materials undergo physical change—that is, the size, shape, appearance, temperature, state or other physical property of the material is altered—or chemical change—that is, a substance with different chemical composition or properties is formed or created. The term includes all of the equipment, operations and facilities necessary for the completion of the transformation of the materials to produce a physical or chemical change. There may be several processes in series or parallel necessary to the manufacture of a product.

e. Process Hold Point – A point at which a process and its associated emissions can be halted without detriment to the safety of the process or quality of the product being produced by the process.

f. Specialty Chemical – a chemical produced for a specialized use and typically manufactured in lower volume than bulk chemicals. Some examples of specialty chemicals may include vitamins, soaps, perfumes, cosmetics, pesticides, specialty cleaning and polishing products.

g. Hazard Index – A summation of the hazard quotients for all chemicals to which an individual is exposed.

8. Plan Approval Fees

This Pharm/Chem General Plan Approval establishes the following fees:

a. Plan approval application fee:

One Thousand Dollars ($1000)

A new authorization and General Plan Approval fee as indicated above is required each time the owner or operator makes a process change that requires construction or modification of sources or use of new HAPs or a change in HAP emissions release characteristics that would affect the ambient air impact analysis required in Condition 13 of this General Plan Approval.

b. Plan approval extension fee:

Three Hundred Dollars ($300)

9. Term, Expiration, and Extension of Plan Approval

a. The General Plan Approval applicant will be issued a letter authorizing the applicant to construct or modify sources and to operate on a temporary basis as specified below.

b. The authorization will be valid for a period of 18 months after the issue date.

c. If the construction, modification or installation is not commenced within 18 months of the issuance of authorization, or if there is more than an 18-month lapse in construction, modification or installation, a new Pharm/Chem General Plan Approval Application and fee shall be submitted.

d. If construction, modification or installation has commenced but cannot be completed before the expiration of the authorization, an extension of the authorization must be obtained to continue construction. To allow adequate time for departmental action, a request for the extension should be postmarked at least thirty (30) days prior to the expiration date. The Department will not issue an extension after the authorization expires. The request for an extension must include a General Plan Approval Application, application fee and the following:

   (i) A justification for the extension; and

   (ii) A schedule for the completion of the construction

e. When the construction, modification, installation or reactivation is nearing completion, the facility owner or operator shall provide written notice to the Department of the completion of the activity approved by this Pharm/Chem General Plan Approval and the facility owner or operator'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 the anticipated date for commencement of operation. When the activity involves multiple sources on different time schedules, notice is required for the commencement of operation of each source.

f. The right to operate under this Pharm/Chem General Plan Approval terminates 180 days from the commencement date of operation unless a Title V Administrative Amendment or Title V renewal application is submitted to the Department thirty (30) days prior to the expiration of the permittee's authorization to operate under this Pharm/Chem General Plan Approval.

g. An extension of the 180-day shakedown period may be requested if further evaluation of the air contamination aspects of the source(s) is necessary. The request for an extension should be submitted, in writing, to the Department at least thirty (30) days prior to the end of the initial 180-day shakedown period and shall include a Pharm/Chem General Plan Approval Application and fee, 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, not to exceed 180 days but may be extended for additional limited periods in accordance with 25 Pa. Code § 127.12b (d) (relating to plan approval terms and conditions).

h. Upon receipt of a complete and timely Administrative Amendment application or Title V renewal application, the Pharm/Chem facility may continue to operate equipment or processes regulated under the Pharm/Chem General Plan Approval subject to final action by the Department on the Administrative Amendment or renewal application. This authorization shall cease to exist if, subsequent to a completeness determination, the applicant fails to submit to the Department any additional information required by the Department to process the application by the deadline specified, in writing, by the Department.

10. Applicable Laws

Nothing in this Pharm/Chem General Plan Approval relieves the facility owner or operator from its obligation to comply with all applicable Federal, state and local laws and regulations.

11. Prohibited Use

The owner or operator of a Title V facility may not use this Pharm/Chem General Plan Approval if the requirements of 25 Pa. Code Chapter 127, Subchapter E (relating to new source review) and 25 Pa. Code Chapter 127, Subchapter D (relating to prevention of significant deterioration) apply to the new or modified source. Use of this Pharm/Chem General Plan Approval is also prohibited if it will cause a Title V facility to exceed its established VOC PAL under the Title V permit.

12. Transfer of Ownership or Operation

This Pharm/Chem General Plan Approval may not be transferred, except as provided in 25 Pa. Code §127.32 (relating to transfer of plan approvals).

13. Restrictions

For the purposes of this Pharm/Chem General Plan Approval, BAT for control of VOC and HAP emissions from any newly constructed or modified source is defined as follows under a. and b. below:

a. PRIMARY OPERATING SCENARIO:

Use of an existing appropriately designed combustion control device such as a Thermal Oxidizing Unit (TOU) for control of combustible VOCs and HAPS which is followed by an existing appropriately designed scrubber for control of acid gases. The combustion control device must achieve 99.9% destruction removal efficiency (DRE) for VOCs and HAPs and 99.99% for methylene chloride. The combustion control device must also achieve the HAP control required by any applicable NESHAP regulations. Scrubbers associated with a combustion control device must meet an overall halogen and hydrogen halide removal efficiency of at least 99%. VOC and/or HAP emissions are not required to be directly vented to a combustion control device where water-reactive compounds, acids or bases are present in vent streams. In these cases, the vent streams shall be controlled by an existing appropriately designed scrubber followed by an existing appropriately designed combustion control device and associated scrubber for the control of VOCs and/or HAPs emissions meeting the above destruction and removal efficiency requirements.

The facility owner or operator shall comply with all monitoring, recordkeeping and reporting requirements applicable to the facility's combustion control device(s) and associated scrubber(s), as specified in the Title V Permit for the facility.

b. SECONDARY OPERATING SCENARIO:

During unplanned combustion control device outages and/or scrubber malfunctions, an alternative operating scenario using a vent condenser meeting the requirements of 25 Pa. Code Section 129.68 (relating to manufacture of synthesized pharmaceutical products) may be employed to complete the processing of batches or material currently in process to the next stable process hold point. However, no new batches may be charged, or processing initiated without using a properly operating combustion control device and scrubber.

i. The facility owner or operator shall maintain the coolant inlet, coolant outlet or exhaust temperature below the value specified in the General Plan Approval Application.

ii. The facility owner or operator shall comply with all monitoring, recordkeeping and reporting requirements applicable to the use of backup controls (e.g. vent condensers) as specified in the Title V Permit for the facility.

iii. The facility owner or operator shall identify and document the stable process hold points for processes, which will make use of the secondary operating scenario.

c. Leak detection:

Except as required by more stringent provisions under Condition No. 15 of this Pharm/Chem General Plan Approval, fugitive VOC and acetone emissions from equipment leaks shall be controlled by conducting weekly inspections of process equipment, during operation, for visible, audible or olfactory indications of leaks. Records of each inspection shall be maintained for a minimum of five (5) years and shall include the results of each inspection and when leaky components have been repaired or replaced. Leaky components shall be repaired or replaced as soon as practicable, but not later than fifteen (15) calendar days after it is detected. Delay of repair for VOC and acetone are allowed if the permittee complies with the requirements of 40 CFR § 63.1255(b)(4)(i) and the facility owner or operator receives written approval from the Department.

d. The facility owner or operator shall comply with all applicable requirements specified in:

i. 40 CFR Part 63 Subpart GGG —National Emission Standards for Pharmaceuticals Production.

ii. 40 CFR Part 63 Subpart MMM—National Emission Standards for Hazardous Air Pollutants for Pesticide Active Ingredient Production.

iii. 40 CFR Part 63 Subpart PPP—National Emission Standards for Hazardous Air Pollutant Emissions for Polyether Polyols Production.

iv. 40 CFR Part 63 Subpart FFFF—National Emission Standards for Hazardous Air Pollutants for Miscellaneous Organic Chemical Manufacturing.

e. The owner or operator of the facility shall submit a list of HAPs to be permitted under this Pharm/Chem General Plan Approval detailing the maximum annual mass quantity of each new HAP and/or increase in existing HAPs to be used along with a human health risk assessment that assesses these HAPs. The human health risk assessment is a scientific process used to estimate the probability of adverse health effects resulting from human exposure to HAPs.

f. The risk assessment must include an air impact modeling analysis. The air impact modeling analysis provides estimates of maximum short-term and long-term ambient air concentrations used to determine the potential for adverse human health effects from inhalation. An air dispersion modeling protocol that describes the selection of the air dispersion model, the actual site conditions and source parameters, and the proposed methods for modeling must be submitted for review and approval by the Department prior to use of this Pharm/Chem General Plan Approval for the permitting of a new or increased HAP which requires a risk assessment. The approval will remain in effect as long as the parameters of the protocol remain unchanged. The risk assessment for approval of new HAP compounds will make use of the acute and chronic endpoint criterion listed below. The results of the approved refined risk assessment shall be submitted to the Department with the General Plan Approval application and fee.

i. The risk assessment must follow the National Academy of Sciences (NAS) paradigm for estimating the risk of contracting cancer and the level of hazard associated with adverse health effects other than cancer. The cancer assessment defines risk as the upper-bound probability of developing cancer from continuous exposure to a HAP at the estimated concentration over a 70-year period. The non-cancer assessment estimates the Hazard Quotient (HQ), which is the potential for non-carcinogenic adverse effects following exposure to a chemical.

ii. Chronic Exposures. For chronic effects, it is assumed that the receptor is continuously exposed to the maximum annual average air concentration of the HAP. To calculate the risk of contracting cancer, or the level of hazard associated with adverse health effects other than cancer, the risk assessment will make use of the HAP specific inhalation Unit Risk Factors (URFs) or Reference Concentration (RfCs). The URFs and RfCs are taken from the table of *Chronic Dose-Response Values for Screening Risk Assessments*, which is published by the U.S. EPA Office of Air Quality Planning and Standards (OAQPS) and is available on-line. The OAQPS tables are appropriate for screening-level risk assessments, including assessments to select contaminants, exposure routes, or emission sources of potential concern, or to help set priorities for further research. The chronic endpoint criterion for carcinogens is a lifetime incremental cancer risk of 1-in-1 million[(1)]. The chronic endpoint criterion for non-carcinogens is a hazard quotient (HQ) of 1[(1)].

iii. Acute Exposures. For acute effects, it is assumed that the receptor is exposed to the maximum 1-hour average air concentration of the HAP. The ambient air concentrations for the acute assessment will be compared against the following endpoint criterion:

Short Term Exposure Limit/40 – STEL/40

Ceiling/10 – C/10 (use this if the STEL is unavailable)

3 x Time Weighted Average/20 – 3 x TWA/20 (use this if the STEL and C are unavailable)

Immediately Dangerous to Life and Health/20 – IDLH/20 (use this if the STEL, C, and TWA are unavailable)

Lethal Concentration 50/100 – LC50/100 (use this if the STEL, C, TWA, and IDLH are unavailable)

The *Acute Dose-Response Values for Screening Risk Assessments,* listed in the most recent versions of the OAQPS tables (use this if the STEL, C, TWA, IDLH, and Lethal Concentration are unavailable).

g. The cancer risk and HQ of each HAP resulting from the aggregation of emissions from all sources of release must not exceed the appropriate endpoint criterion in order to be approved for use. In addition, the hazard index (HI) and cumulative risk must not exceed the appropriate endpoint criterion of 1 (HI) and 1-in-1 million cancer risk in order to be approved for use. The maximum 1-hour average air concentration of each HAP, resulting from the aggregation of emissions from all sources of release, must not exceed the appropriate endpoint criterion in order to be approved for use.

h. If a source fails the risk assessment, the facility owner or operator will schedule a formal review with the Department to evaluate the risk assessment to determine whether and/or how the source's permit should be approved. Sources with a risk exceeding the thresholds specified in this Pharm/Chem General Plan Approval will typically require authorization in accordance with 25 Pa. Code Chapter 127, Subchapter B (relating to plan approval requirements).

i. Each time new construction or a process change is made such that the quantity of existing HAPs released increases above the previously submitted maximum annual mass quantity or a new HAP is emitted, a new ambient air impact analysis must be performed on each HAP, and submitted to the Department along with the General Plan Approval application and fee to demonstrate that the ambient air concentrations do not exceed the appropriate endpoint criterion.

14. Testing Requirements

a. Within 180 days of receiving Department approval to use this Pharm/Chem General Plan Approval, performance testing of the combustion control device and associated scrubber shall be performed when a process change causes an increase in emission loading to the existing air pollution control device(s). Stack testing shall be performed to verify that the new or increased VOC and/or HAP loading to the existing control system will result in the destruction or removal efficiency required. Also, parameters such as oxidizer temperature, scrubber flow rate and pH shall be verified to be adequate at the new or increased VOC and/or HAP loading. The stack testing only needs to be performed if the proposed VOC and/or HAP loading is determined to be higher than the loading to the control device(s) during a previous stack test. All testing shall be performed in accordance with the provisions of 25 Pa. Code Chapter 139 (relating to sampling and testing).

b. At least sixty (60) calendar days prior to commencing an emissions testing program required by this Pharm/Chem General Plan Approval, two (2) copies of a test protocol shall be submitted to the Department's appropriate Regional Office for review and approval. The test protocol shall meet all applicable requirements specified in the most current version of the Department's Source Testing Manual.

c. At least fifteen (15) calendar days prior to commencing an emission testing program required by this Pharm/Chem General Plan Approval, written notification of the date and time of testing shall be provided to the Department's appropriate Regional Office. Notification, in writing, shall also be sent to the Department's Bureau of Air Quality, Division of Source Testing and Monitoring. The notification shall not be made without prior receipt of a protocol acceptance letter from the Department. The Department is under no obligation to accept the results of any testing performed without adequate advance written notice to the Department of such testing.

d. Within fifteen (15) calendar days after completion of the on-site testing portion of an emission test program required by this Pharm/Chem General Plan Approval, if a complete test report has not yet been submitted to the Department, an electronic mail notification shall be sent to the Department's Division of Source Testing and Monitoring indicating the completion date of the on-site testing.

e. Two (2) copies of a complete test report shall be submitted to the Department's appropriate Regional Office no later than 60 calendar days after completion of the on-site testing portion of an emission test program required by this Pharm/Chem General Plan Approval. The test report shall meet all applicable requirements specified in the most current version of the Department's Source Testing Manual, including the results of the tests, a description of the testing and analytical procedures actually used in performance of the tests, all process and operating data collected during the tests, a copy of all raw data, and a copy of all calculations generated during data analysis.

f. A complete test report shall include a summary of the emission results on the first page of the report indicating if each pollutant measured is within permitted limits and a statement of compliance or non-compliance with all applicable permit conditions. The summary results will include, at a minimum, the following information:

   i. A statement that the owner or operator has reviewed the report from the emissions testing body and agrees with the findings.
   ii. Plan Approval and Permit number(s) and condition(s) which are the basis for the evaluation.
   iii. Summary of results with respect to each applicable permit condition.
   iv. Statement of compliance or non-compliance with each applicable permit condition.
   v. Parameters measured and verified according to Condition 14.a.

g. All submittals, except notifications, shall be accomplished through PSIMS*Online available through https://www.depgreenport.state.pa.us/ecomm/Login.jsp when it becomes available. If internet submittal can not be accomplished, paper copies shall be submitted as specified in paragraphs a, e and f above.

15. Monitoring Requirements

a. The facility owner or operator shall, pursuant to the National Emission Standards for Hazardous Air Pollutants (NESHAP) of 40 CFR Part 63 and the BAT provisions of 25 Pa. Code §§ 127.1 and 127.12, initiate leak detection and repair (LDAR) programs compliant with NESHAP and 25 Pa. Code §§129.68 and 129.71, and the facility's Title V Permit, in order to minimize fugitive organic emissions from any source that has potential to generate fugitive organic emissions.

b. The following emission estimation methods may be used to produce the most accurate emissions estimate for sources to verify compliance with the PAL and emission limitations in the site's Title V permit and this Pharm/Chem General Plan Approval:

i. Combustion control device emissions may be estimated using continuous monitoring systems, stack test results, AP-42 emission factors, or vendor emission factors.

ii. Emissions from wastewater treatment equipment may be estimated using the TOXCHEM model or EPA's Water 8 model.

iii. Specialty chemical production and pharmaceutical production process vent emissions may be estimated using 1978 CTG or 1994 ACT equations if no source-specific testing or emission factors are available.

iv. Filling and breathing losses from bulk storage tanks may be estimated using Section 7 of AP-42, EPA's TANKS program, or the storage tanks portion of the CAIMS program.

v. Fugitive emissions may be estimated using SOCMI fugitive emission factors or company-specific fugitive emission factors approved by the department.

vi. The use of other methods of emission estimation, beyond those listed above, approved by the Department.

16. Recordkeeping Requirements

a. <u>PRIMARY OPERATING SCENARIO</u>

i. The facility owner or operator shall comply with all monitoring, recordkeeping and reporting requirements applicable to the permittee's combustion control device(s) and associated scrubber(s) as specified in the permittee's Title V permit.

ii. The facility owner or operator shall keep records of the amount of time that the combustion control device(s) and associated scrubber(s) are not available (i.e., downtime) each month when producing emissions. Records shall also be maintained each month stating that the processing stopped at the next stable hold point and that no new batches were started during control device malfunction. The records must also identify the batches in process during control device malfunction and identify the stable process hold point where processing ceased. The records shall include the date and time that the control device is not available and the date and time that the control device is back online.

b. <u>SECONDARY OPERATING SCENARIO</u>

i. The facility owner or operator shall comply with all monitoring, recordkeeping and reporting requirements applicable to the use of backup controls (e.g. vent condensers) or primary controls (e.g. scrubbers) as specified in the permittee's Title V permit.

ii. The facility owner or operator shall identify and document the stable process hold points for processes which will make use of the secondary operating scenario.

iii. The facility owner or operator shall keep records of the amount of time that the TOU is not available (i.e., downtime) each month when producing emissions. The records shall include the date and time that the TOU is not available and the date and time that the TOU is back online.

c. These records shall be retained for at least five (5) years and shall be made available to the Department upon request.

17. Reporting Requirements

a. The facility owner or operator shall report malfunctions that occur at this facility to the Department. 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 that may result in an increase in the emissions of air contaminants. Failures that are caused in part by poor maintenance or careless operation are not malfunctions.

b. Failures that are caused in part by poor maintenance or careless operation shall be reported as excess emissions or deviations from this General Plan Approval's requirements.

c. When the malfunction, excess emissions or deviation from this General Plan Approval's requirements poses an imminent and substantial danger to the public health and safety or the environment, the owner or operator shall notify the Department by telephone no later than one (1) hour after the incident.

d. Unless otherwise required by the specific reporting requirements, any malfunction, excess emissions or deviation from General Plan Approval's requirements that is not subject to the notice requirements of subsection (c) of this General Plan Approval condition shall be reported to the Department by the next business day following discovery. The reports submitted to the Department shall include the following:

i. Name and location of the facility;

ii. Nature and cause of the malfunction or breakdown;

iii. Time when the malfunction or breakdown was first observed;

iv. Expected duration of excess emissions;

v. Estimated rate of emissions; and

vi. Corrective actions or preventative measures taken.

e. The facility owner or operator shall notify the Department immediately when corrective measures have been accomplished.

f. Upon the request of the Department, the facility owner or operator shall submit a full written report to the Regional Air Program Manager within fifteen (15) days of the malfunction, excess emissions or deviations from the requirements of this General Plan Approval.

Approved by: _____

Joyce E. Epps
Director
Bureau of Air Quality

Date approved: _____