**Facility Identification Data**
Name: WYETH PHARMACEUTICALS
Address: 64 MAPLE ST
ROUSES POINT, NY 12979

**Owner/Firm**
Name: WYETH PHARMACEUTICALS INC
Address: 64 MAPLE ST
ROUSES POINT, NY 12979-1424, USA
Owner Classification: Corporation/Partnership

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## Permit Description

### Introduction

The Title V operating air permit is intended to be a document containing only enforceable terms and conditions as well as any additional information, such as the identification of emission units, emission points, emission sources and processes, that makes the terms meaningful. 40 CFR Part 70.7(a)(5) requires that each Title V permit have an accompanying "...statement that sets forth the legal and factual basis for the draft permit conditions". The purpose for this permit review report is to satisfy the above requirement by providing pertinent details regarding the permit/application data and permit conditions in a more easily understandable format. This report will also include background narrative and explanations of regulatory decisions made by the reviewer. It should be emphasized that this permit review report, while based on information contained in the permit, is a separate document and is not itself an enforceable term and condition of the permit.

**Summary Description of Proposed Project**
Application for renewal of Air Title V Facility.

The application included no new emissions or significant changes in actual potential to emit. However, reevaluation of active particulate ingredient (APIs) emissions did identify API emissions from existing sources not previously considered as API sources.

Removal of permit condition requiring maximum temperature of -25C for Glatt Coaters process condensers (ES M00056, M0233, and M0307). This condition became obsolete when these sources were tied in to the RTOs.

For EUs 00003 & 00006 / EPs 00034, 00035, 00036, 00037, 00040, 00102 and 00103 and corresponding source/control were removed from permit. These EPs and sources are presently used for R&D purposes only. EPs 00102 and 00103 sources/controls include ES 00078, 00079, 00080, 00081, 00082 and 00083.

EU 00003/ES 00025, 00027, 00028, 00029, 00030, 00031, 00032, 00033, 00034, and 00035, and EU 00004/ES 00093 and 00112 were removed by this application.

EU 00003, EP 00187 was added to permit. Emissions exhausted from this EP are fugitive non-API particulate emissions when materials are added to coating solution tanks. Similarly, ES 00398 was added for non-API fugitives from the coating solution tanks associated with Building 25 Accela-Cota pan. ES 000398 exhausts through permitted EP 00167. Also added to the permit and exhausted through EP 00167 is ES 00399, which has a potential to emit APIs.

The following sources/controls were added to the permit; EU 00003/ES 00400 & 00401 and EU 00005/ES 00402. These sources/controls have a potential to emit APIs and exhaust through emission points 00156 & 00115, respectively.

The following emission points were added to the permit: EU 00013 / EPs 00188, 00190 (PAL 4) & 00189, 00191 (PAL7). These emission points are used only in aqueous mode during granulation and fluid bed drying to vent PM. This PM may contain APIs.

An op-flex provision was added to permit to incorporate a protocol by which Wyeth can evaluate proposed minor modifications for compliance with applicable requirements. The protocol includes provisions for notifying the Department prior to commencing the modification. Modification made under an approved protocol are not subject to the provisions of Section 201-6.7.

A compliance certification activity requiring parametric monitoring was added to VOC scrubbers (ES 00152 & 00231) to provide reasonable compliance assurance with the VOC cap.

Compliance certification activities were revised/added to provide reasonable compliance assurance with opacity and particulate standards specified in Part 212 for sources with a potential to emit B & C - rated particulate. These activities included an enhanced record keeping/reporting and visible emissions observations (VEO).

Compliance certification activities for existing permitted API sources were revised/added to provide reasonable compliance assurance. Included in these compliance certification activities are some additional existing sources not previously identified as emitting APIs. Only the sources identified in these certification activities are permitted for API emissions. As part of the permit renewal process, an annual guideline concentration (AGC) was specifically developed for A - rated APIs currently emitted. This AGC was compared to impacts, predicted by an approved air dispersion model of the facility's estimated mass emission rates from the permitted API sources (including contributions from exempt sources), to determine compliance with 6NYCRR 212.9 (b) Table 2.

Control equipment upgrades were included in the permit for control sources ESs. 00003, 00009, 00011, 00174, 00228 and 00266 to mitigate ambient impacts from API sources. In addition, various DAS upgrades were required to better provide for reasonable compliance assurance.

**Attainment Status**

WYETH PHARMACEUTICALS is located in the town of CHAMPLAIN in the county of CLINTON.
The attainment status for this location is provided below. (Areas classified as attainment are those that meet all ambient air quality standards for a designated criteria air pollutant.)

| Criteria Pollutant | Attainment Status |
|---|---|
| Particulate Matter (PM) | ATTAINMENT |
| Particulate Matter < 10µ in diameter (PM10) | ATTAINMENT |
| Sulfur Dioxide (SO2) | ATTAINMENT |
| Ozone* | TRANSPORT REGION (NON-ATTAINMENT) |
| Oxides of Nitrogen (NOx)** | ATTAINMENT |
| Carbon Monoxide (CO) | ATTAINMENT |

* Ozone is regulated in terms of the emissions of volatile organic compounds (VOC) and/or oxides of nitrogen (NOx) which are ozone precursors.
** NOx has a separate ambient air quality standard in addition to being an ozone precursor

**Facility Description**
Wyeth-Ayerst Pharmaceuticals, Incorporated is a pharmaceutical manufacturing facility located in Clinton County, New York, Town of Champlain. The facility is primarily engaged in the formulation and packaging of pharmaceutical preparations for human and veterinary use. The majority of products are finished in their final dosage forms. The facility also manufactures pharmaceutical products by chemical synthesis and extraction, and conducts research and development activities.

Emissions of Nitrogen Oxides (NOx) and Sulfur Dioxide (SO2) from the facility are each capped at 99 tons per year (tpy). Therefore, the control requirements contained in 6 NYCRR Subpart 227-2, Reasonably Available Control Technology (RACT) for NOx, and 40 CFR 52, Federal Prevention of Significant Deterioration of Air Quality (PSD) do not presently apply to sources at the facility. In addition, emissions of Volatile Organic Compounds (VOC's) from the facility are capped at 49 tpy, such that the VOC RACT provisions of 6 NYCRR Section 212.10, as well as VOC RACT provisions in other rules (e.g., 6 NYCRR Parts 228 and 233) which are triggered by a facility-wide Potential To Emit (PTE) VOC's over 50 tpy do not apply. They are still, however, subject to certain VOC RACT requirements triggered when the facility's PTE for VOC's is over 10 tpy. Finally, through particulate emission limits or control efficiencies set on each process emission point, a preventative maintenance requirement on all particulate control devices and boiler fuel use limitations resulting from the above NOx and SO2 emission limits, the facility's potential to emit particulate matter less than 10 microns in diameter (PM-10) is less than the 100 tpy major source threshold.

This permit establishes a cap on emissions of Hazardous Air Pollutants (HAPs). The cap limits facility-wide emissions of any individual HAP to less than 10 tons per year (tpy) and combined HAPs to less than 25tpy. Therefore, the pharmaceutical manufacturing operations at the facility are not subject to 40CFR 63, Subpart GGG requirements. Emissions of such pollutants will, therefore, primarily be regulated under 6NYCRR Part 212 and/or 200.

**Permit Structure and Description of Operations**
The Title V permit for WYETH PHARMACEUTICALS

is structured in terms of the following hierarchy: facility, emission unit, emission point, emission source and process.
A facility is defined as all emission sources located at one or more adjacent or contiguous properties owned or operated by the same person or persons under common control. The facility is subdivided into one or more emission units (EU). Emission units are defined as any part or activity of a stationary facility that emits or has the potential to emit any federal or state regulated air pollutant. An emission unit is represented as a grouping of processes (defined as any activity involving one or more emission sources (ES) that emits or has the potential to emit any federal or state regulated air pollutant). An emission source is defined as any apparatus, contrivance or machine capable of causing emissions of any air contaminant to the outdoor atmosphere, including any appurtenant exhaust system or air cleaning device. [NOTE: Indirect sources of air contamination as defined in 6 NYCRR Part 203 (i.e. parking lots) are excluded from this definition]. The applicant is required to identify the principal piece of equipment (i.e., emission source) that directly results in or controls the emission of federal or state regulated air pollutants from an activity (i.e., process). Emission sources are categorized by the following types:

combustion - devices which burn fuel to generate heat, steam or power
incinerator - devices which burn waste material for disposal
control - emission control devices
process - any device or contrivance which may emit air contaminants that is not included in the above categories.

WYETH PHARMACEUTICALS is defined by the following emission unit(s):
Emission unit 000001 - Facility boilers - Emission Unit consists of four (4) steam generating boilers each with a maximum rated heat input capacity greater than 50 million btu per hour and equal to or less than 100 million btu per hour. Each has the capability to be fired with natural gas or No. 2 fuel oil (PR Nos. 001 and 01C). Three are subject to 40 CFR 60, Subpart Dc - ES Nos. 00074, 00204 and 00333 at 73, 84.5 and 98 million Btu/hr heat input capacity, respectively. The fourth boiler (ES No. 00001) predates 40 CFR 60, Subpart Dc and has a heat input capacity of 55.9 million Btu/hr. Each of these four boilers has its own stack (EP Nos. 00100, 00149, 00172 and 00001).
Emission unit 000001 is associated with the following emission points (EP):
00001, 00100, 00149, 00172
It is further defined by the following process(es):
Process: 001 is located at Building 6 - 4 Natural gas fired steam generating boilers, each with a maximum rated heat input capacity greater than 50 million Btu's per hour and equal to or less than 100 million Btu's per hour.
Process: 01C is located at Building 6 - 4 No. 2 fuel oil fired steam generating boilers, each with a maximum rated heat input capacity of greater than 50 million Btu's per hour and equal to or less than 100 million Btu's per hour.

Emission unit 000002 - Chemical Pilot Plant production equipment exhaust system (PEES) - This Emission Unit consists of localized equipment pickups, primarily used to reduce worker exposure.
Emission unit 000002 is associated with the following emission points (EP):
00033, 00072, 00110, 00132, 00179
It is further defined by the following process(es):
Process: 003 is located at Building 23 - This process consists of intermittent production activities conducted using Chemical Pilot Plant Equipment.

Emission unit 000003 - Main Plant production equipment exhaust system (PEES) - This Emission Unit consists of localized equipment pickups, primarily used to reduce worker exposure. This unit also contains the House Vacuum system utilized to clean production area floors and equipment.
Emission unit 000003 is associated with the following emission points (EP):
00009, 00014, 00015, 00016, 00017, 00019, 00024, 00031, 00082, 00120, 00124, 00138, 00139, 00143, 00152, 00156, 00157, 00162, 00164, 00167, 00168, 00185, 00186, 00187

It is further defined by the following process(es):
Process: 004 is located at Building 21 - Tablet coating solution area production exhaust system. Additional building no. 18 and 27.
Process: 005 is located at Building 14 - House vacuum systems used for cleaning building and machinery surfaces. Additional building nos. 4a,15,21,20,32, 27, & 35.
Process: 006 is located at Building 20 - Production exhaust systems. Additional building nos. 3ai, 4a, 13, 14, 21, 18, 19, 25, & 35.

Emission unit 000004 - Sources tributary to Building 27 Dust Collector (EP 00106) - This Emission Unit consists of a dust collection system that ventilates room and equipment exhausts in the solids dosage manufacturing area. All of these exhausts are routed to a common dust collector.
Emission unit 000004 is associated with the following emission points (EP):
00106, 00180, 00181
It is further defined by the following process(es):
Process: 007 is located at Building 27 - Pharmaceutical manufacturing operations are vented to a common dust collector and stack (EP#00106) with the exception of the Charging (ES00375) and Pack-Off (ES00376) Isolators. The Charging and Pack-off isolators are controlled by HEPA filters (ES 000377 & 000378) and vented through EPs 00180 and 00181, respectively.

Emission unit 000005 - Air Dryers - This Emission Unit consists of dryers and ovens utilized in the drying of pharmaceutical products.
Emission unit 000005 is associated with the following emission points (EP):
00075, 00115, 00128, 00129, 00130, 00141, 00165, 00166
It is further defined by the following process(es):
Process: 008 is located at Building 32 - Tray dryers used in pharmaceutical manufacturing. Additional buildings nos. 14 & 21.
Process: 009 is located at Building 13 - Air dryers used in pharmaceutical manufacturing. Additional buildings nos. 27, 14, 32, 35, 27, & 21.

Emission unit 000006 - Tablet Coating - This Emission Unit consists of equipment utilized in the sealing, coating, and polishing of pharmaceutical tablets.
Emission unit 000006 is associated with the following emission points (EP):
00101, 00111, 00118, 00119, 00122, 00125, 00127, 00147, 00148, 00150, 00151, 00158, 00160, 00161, 00163, 00173, 00174, 00176, 00177, 00178, 00183
It is further defined by the following process(es):
Process: 011 is located at Building 18 - Procoater coating pans used for the coating of formed pharmaceutical products. Additional building nos. 27 and 21.
Process: 012 is located at Building 32 - Tablet coating pans used for coating formed pharmaceutical products with scrubber control. Additional building no. 21.
Process: 013 is located at Building 14 - Tablet coating pans used for coating formed pharmaceutical products. Additional building no. 32.
Process: 014 is located at Building 14 - Accela cota coating pans used for coating of formed pharmaceutical products. Additional building nos. 32 and 18.

Emission unit 000008 - Tank Farm - This Emission Unit consists of five (5) Chemical Bulk Storage Tanks storing one of the following chemicals: acetone; methanol; isopropanol; or toluene. This unit also contains three (3) hazardous waste tanks which store waste acetone and mixed solvents.
Emission unit 000008 is associated with the following emission points (EP):
00039, 00043, 00044, 00045, 00046, 00047, 00048, 00049
It is further defined by the following process(es):
Process: 016 is located at Building TF - Vapor losses from chemical bulk storage tanks.

Emission unit 000009 - Chemical Pilot Plant process equipment sources - This Emission Unit consists of reactor

series' with both atmospheric and vacuum operations, centrifuge, and tray dryers vented to 1 of 4 types of vapor condensers and/or a process scrubber. Emissions from all processes (PR ID's 017, 17B, 17C, 021 and 21B) are vented primarily though the GEP stack (EP 00144). However, process scrubbers (ES Nos. 00325-00330) may, in some instances be vented through individual non-GEP stacks (EP Nos. 00062, 00063, 00073, 00091, 00093 and 00096) provided they meet all applicable regulatory requirements while doing so. The unit also contains a wastewater treatment system consisting of pH neutralization and steam stripping unit operations emitted through EP No. 00144.
Emission unit 000009 is associated with the following emission points (EP):
00062, 00063, 00073, 00091, 00093, 00096, 00144
It is further defined by the following process(es):
Process: 017 is located at Building 31 - Chemical pilot plant atmospheric reactor operations with low temperature condenser controls.
Process: 021 is located at Building 31 - Treatment of main plant and/or Chemical Development wastewater containing <1% organic solvents. Treatment will include pH neutralization and steam stripping unit operations as needed. Additional Building 26.
Process: 17B is located at Building 31 - Chemical pilot plant vacuum reactor operations with low temperature condenser controls.
Process: 17C is located at Building 31 - Chemical pilot plant vacuum tray dryers.
Process: 21B is located at Building 31 - Treatment of Chemical Development wastewater containing up to 15% organic solvents. Treatment will include pH neutralization and steam stripping unit operations as needed. Additional Building 26.

Emission unit 000011 - Chemical Pilot Plant Miscellaneous Sources - This Emission Unit consists of a Heat Transfer Media Expansion Tank.
Emission unit 000011 is associated with the following emission points (EP):
00097
It is further defined by the following process(es):
Process: 019 is located at Building 26 - Expansion tank for silicone oil heat transfer media.

Emission unit 000013 - This Emission Unit consists of existing pharmaceutical manufacturing processes that will be vented to a regenerative thermal oxidizer (RTO) and scrubber system. The RTO / scrubber system consists of two RTOs that will be used alternately or simultaneously to reduce emissions. Each RTO will be equipped with a caustic scrubber and exhaust through a common exhaust stack. Existing process emissions and room air exhaust from affected sources will be diverted to a rooftop header feeding the RTOs. Air streams containing particulate matter will pass through dedicated dust collectors and HEPA filters prior to entering the RTO header.

This emission unit also includes aqueous granulation processes in PAL 4 and 7. In addition to particulate emissions from fluid bed dryers (FBDs) (EPs 00188 & 00189) fugitive emissions from other granulation activities are also captured by dedicated dust collection systems. These emissions are exhausted to the atmosphere (EPs 00190 & 00191) in aqueous mode instead of being directed to the RTO.
Emission unit 000013 is associated with the following emission points (EP):
00175, 00188, 00189, 00190, 00191
It is further defined by the following process(es):
Process: 022 is located at Building 36A - Various Pharmaceutical Coating and Granulation activities vented to regenerative thermal oxidizer/scrubber control system for control of VOC and HAP emissions.
Process: 023 is located at Building 36A - This process represents aqueous (non-solvent) granulation processes in PAL 4 and 7. In addition to particulate emissions from fluid bed dryers (FBDs) (EPs 00188 & 00189) fugitive emissions from other granulation activities are also captured by dedicated dust collection systems. These emissions are exhausted to the atmosphere (EPs 00190 & 00191) in aqueous mode instead of being directed to the RTO. These are potential sources for Active Particulate Ingredients (APIs).

**Title V/Major Source Status**
WYETH PHARMACEUTICALS is subject to Title V requirements. This determination is based on the following information:
This facility was a major source of Hazardous Air Pollutants (HAP's) when the original Title V permit was issued. This permit, however, caps potential emissions of HAP's below the major source thresholds of 10 tons per year (tpy) for any individual HAP and 25 tpy of combined HAP's. The facility is no longer major for any regulated air contaminant.

**Program Applicability**
The following chart summarizes the applicability of WYETH PHARMACEUTICALS with regards to the principal air pollution regulatory programs:

| Regulatory Program | Applicability |
|---|---|
| PSD | NO |
| NSR (non-attainment) | NO |
| NESHAP (40 CFR Part 61) | NO |
| NESHAP (MACT - 40 CFR Part 63) | NO |
| NSPS | YES |
| TITLE IV | NO |
| TITLE V | YES |
| TITLE VI | NO |
| RACT | YES |
| SIP | YES |

NOTES:
PSD Prevention of Significant Deterioration (40 CFR 52) - requirements which pertain to major stationary sources located in areas which are in attainment of National Ambient Air Quality Standards (NAAQS) for specified pollutants.

NSR New Source Review (6 NYCRR Part 231) - requirements which pertain to major stationary sources located in areas which are in non-attainment of National Ambient Air Quality Standards (NAAQS) for specified pollutants.

NESHAP National Emission Standards for Hazardous Air Pollutants (40 CFR 61) - contaminant and source specific emission standards established prior to the Clean Air Act Amendments of 1990 (CAAA) which were developed for 9 air contaminants (inorganic arsenic, radon, benzene, vinyl chloride, asbestos, mercury, beryllium, radionuclides, and volatile HAP’s)

MACT Maximum Achievable Control Technology (40 CFR 63) - contaminant and source specific emission standards established by the 1990 CAAA. Under Section 112 of the CAAA, the US EPA is required to develop and promulgate emissions standards for new and existing sources. The standards are to be based on the best demonstrated control technology and practices in the regulated industry, otherwise known as MACT. The corresponding regulations apply to specific source types and contaminants.

NSPS New Source Performance Standards (40 CFR 60) - standards of performance for specific stationary source categories developed by the US EPA under Section 111 of the CAAA. The standards apply only to those stationary sources which have been constructed or modified after the regulations have been proposed by publication in the Federal Register and only to the specific contaminant(s) listed in the regulation.

Title IV Acid Rain Control Program (40 CFR 72 thru 78) - regulations which mandate the implementation of the acid rain control program for large stationary combustion facilities.

Title VI Stratospheric Ozone Protection (40 CFR 82, Subparts A thru G) - federal requirements that apply to sources which use a minimum quantity of CFC's (chlorofluorocarbons), HCFC's(hydrofluorocarbons)or other ozone depleting substances or regulated substitute substances in equipment such as air conditioners, refrigeration equipment or motor vehicle air conditioners or appliances.

RACT Reasonably Available Control Technology (6 NYCRR Parts 212.10, 226, 227-2, 228, 229, 230, 232, 233, 234, 235, 236) - the lowest emission limit that a specific source is capable of meeting by application of control technology that is reasonably available, considering technological and economic feasibility. RACT is a control strategy used to limit emissions of VOC's and NOx for the purpose of attaining the air quality standard for ozone. The term as it is used in the above table refers to those state air pollution control regulations which specifically regulate VOC and NOx emissions.

SIP State Implementation Plan (40 CFR 52, Subpart HH) - as per the CAAA, all states are empowered and required to devise the specific combination of controls that, when implemented, will bring about attainment of ambient air quality standards established by the federal government and the individual state. This specific combination of measures is referred to as the SIP. The term here refers to those state regulations that are approved to be included in the SIP and thus are considered federally enforceable.

**Compliance Status**

Facility is in compliance with all requirements

**SIC Codes**

SIC or Standard Industrial Classification code is an industrial code developed by the federal Office of Management and Budget for use, among other things, in the classification of establishments by the type of activity in which they are engaged. Each operating establishment is assigned an industry code on the basis of its primary activity, which is determined by its principal product or group of products produced or distributed, or services rendered. Larger facilities typically have more than one SIC code.

| SIC Code | Description |
|---|---|
| 2833 | MEDICINALS AND BOTANICALS |
| 2834 | PHARMACEUTICAL PREPARATIONS |
| 2835 | DIAGNOSTIC SUBSTANCES |
| 2836 | BIOLOGICAL PRODUCTS, EXCEPT DIAGNOSTIC |

2842 POLISHES AND SANITATION GOODS

**SCC Codes**

SCC or Source Classification Code is a code developed and used" by the USEPA to categorizeprocesses which result in air emissions for the purpose of assessing emission factor information.Each SCC represents a unique process or function within a source category logically associated with a point of air pollution emissions. Any operation that causes air pollution can be represented by one or more SCC's.

| SCC Code | Description |
|---|---|
| 3-01-060-09 | CHEMICAL MANUFACTURING<br>CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS<br>Air Dryers |
| 3-01-060-11 | CHEMICAL MANUFACTURING<br>CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS<br>Coating Process |
| 3-01-060-08 | CHEMICAL MANUFACTURING<br>CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS<br>Exhaust Systems |
| 3-01-060-04 | CHEMICAL MANUFACTURING<br>CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS<br>Filters |
| 3-01-060-12 | CHEMICAL MANUFACTURING<br>CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS<br>Granulation Process |
| 3-01-060-02 | CHEMICAL MANUFACTURING<br>CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS<br>Reactors |
| 3-01-820-01 | CHEMICAL MANUFACTURING<br>CHEMICAL MANUFACTURING - WASTEWATER AGGREGATE<br>Wastewater Stripper |
| 1-02-005-01 | EXTERNAL COMBUSTION BOILERS - INDUSTRIAL<br>INDUSTRIAL BOILER - DISTILLATE OIL<br>Grades 1 and 2 Oil |
| 1-02-006-01 | EXTERNAL COMBUSTION BOILERS - INDUSTRIAL<br>INDUSTRIAL BOILER - NATURAL GAS<br>Over 100 MBtu/Hr |
| 4-07-080-97 | ORGANIC CHEMICAL STORAGE<br>ORGANIC CHEMICAL STORAGE - FIXED ROOF TANKS - NITRO COMPOUNDS<br>Specify in Comments: Breathing Loss |
| 4-07-080-98 | ORGANIC CHEMICAL STORAGE<br>ORGANIC CHEMICAL STORAGE - FIXED ROOF TANKS - NITRO COMPOUNDS<br>Specify in Comments: Working Loss |

**Facility Emissions Summary**

In the following table, the CAS No. or Chemical Abstract Series code is an identifier assigned to every chemical compound. [NOTE: Certain CAS No.'s contain a 'NY' designation within them. These are not true CAS No.'s but rather an identification which has been developed by the department to identify groups of contaminants which ordinary CAS No.'s do not do. As an example, volatile organic compounds or VOC's are identified collectively by the NY CAS No. 0NY998-00-0.] The PTE refers to the Potential to Emit. This is defined as the maximum capacity of a facility or air contaminant source to emit any air contaminant under its physical and operational design. Any physical or operational limitation on the capacity of the facility or air contamination source to emit any air contaminant , including air pollution control equipment and/or restrictions on the hours of operation, or on the type or amount or material combusted, stored, or processed, shall be treated as part of the design only if the limitation is contained in federally enforceable permit conditions. The PTE Range represents an emission range for a contaminant. Any PTE quantity that is displayed represents a facility-wide emission cap or limitation for that

contaminant. If no PTE quantity is displayed, the PTE Range is provided to indicate the approximate magnitude of facility-wide emissions for the specified contaminant in terms of tons per year (tpy). The term 'HAP' refers to any of the hazardous air pollutants listed in section 112(b) of the Clean Air Act Amendments of 1990. Total emissions of all hazardous air pollutants are listed under the special NY CAS No. 0NY100-00-0. In addition, each individual hazardous air pollutant is also listed under its own specific CAS No. and is identified in the list below by the (HAP) designation.

| Cas No. | Contaminant Name | PTE | | | | |
|---|---|---|---|---|---|---|
| | | lbs/yr | | Range | | |
| 000111-26-2 | 1- HEXALYAMINE | 19000 | | A | | |
| 000092-52-4 | 1, 1 BIPHENYL | 49000 | | Y | | |
| 000107-06-2 | 1,2-DICHLOROETHANE | 19000 | | Y | | |
| 000123-31-9 | 1,4-BENZENEDIOL | 19000 | | Y | | |
| 000123-91-1 | 1,4-DIETHYLENE DIOXIDE | 198000 | | Y | | |
| 000111-49-9 | 1H-AZEPINE,HEXAHYDRO- | 198000 | | A | | |
| 000496-15-1 | 1H-INDOLE,2,3-DIHYDRO- | 98000 | | A | | |
| 000109-01-3 | 1-METHYL PIPERAZINE | pteyear | | A | | |
| 001476-23-9 | 1-PROPENE, 3-ISOCYANATO | pteyear | | A | | |
| 000109-09-1 | 2-CHLOROPYRIDINE | pteyear | | A | | |
| 000109-86-4 | 2-METHOXYETHANOL | pteyear | | Y | | |
| 000108-10-1 | 2-PENTANONE, 4-METHYL | pteyear | | Y | | |
| 000075-31-0 | 2-PROPANAMINE | pteyear | | E | | |
| 007087-68-5 | 2-PROPANAMINE, N-ETHYL-N-(1-METHYLETHYL) | | | pteyear | | A |
| 000107-18-6 | 2-PROPEN-1-OL | pteyear | | A | | |
| 000156-87-6 | 3-AMINO-1-PROPANOL | pteyear | | A | | |
| 005231-87-8 | 3-CYCLOBUTENE-1,2-DIONE,3,4, DIETHOXY | | pteyear | | A | |
| 000625-31-0 | 4-PENTEN-2-OL | pteyear | | A | | |
| 000075-07-0 | ACETALDEHYDE | pteyear | | Y | | |
| 000064-19-7 | ACETIC ACID | pteyear | | A | | |
| 000107-59-5 | ACETIC ACID, CHLORO-,TERT-BUTYL ESTER | | pteyear | | B | |
| 000076-05-1 | ACETIC ACID, TRIFLUORO- | pteyear | | A | | |
| 000075-05-8 | ACETONITRILE | pteyear | | Y | | |
| 000107-14-2 | ACETONITRILE, CHLORO | pteyear | | A | | |
| 007664-41-7 | AMMONIA | pteyear | | B | | |
| 000062-53-3 | ANILINE | pteyear | | Y | | |
| 028556-81-2 | BENZENE, 2-ISOCYANATO-1,3-DIMETHYL- | | pteyear | | A | |
| 000104-47-2 | BENZENEACETONITRILE, 4-METHOXY- | | pteyear | | A | |
| 000100-39-0 | BENZYL BROMIDE | pteyear | | A | | |
| 000100-44-7 | BENZYL CHLORIDE | pteyear | | Y | | |
| 010294-34-5 | BORANE, TRICHLORO | pteyear | | A | | |
| 000109-63-7 | BORON,TRIFLUORO[1,1'-OXYBIS[ETHANE]],(T-4)- | | | pteyear | | A |
| 007726-95-6 | BROMINE | pteyear | | A | | |
| 005332-06-9 | BUTANENITRILE, 4-BROMO- | pteyear | | A | | |
| 000630-08-0 | CARBON MONOXIDE | pteyear | | F | | |
| 007782-50-5 | CHLORINE | pteyear | | Y | | |
| 000067-66-3 | CHLOROFORM | pteyear | | Y | | |
| 002719-27-9 | CYCLOHEXANE CARBONYL CHLORIDE | | pteyear | | A | |
| 000108-94-1 | CYCLOHEXANONE | pteyear | | D | | |
| 000137-43-9 | CYCLOPENTANE BROMIDE | pteyear | | B | | |
| 000930-28-9 | CYCLOPENTANE CHLORIDE | pteyear | | A | | |
| 024424-99-5 | DICARBONIC ACID, BIS(1,1-DIMETHYLETHYL) ESTER | | | pteyear | | A |
| 000075-09-2 | DICHLOROMETHANE | pteyear | | | | |
| 001501-06-0 | DIETHYL 2-ACETYL GLU | pteyear | | A | | |
| 001972-28-7 | DIETHYL AZODICARBOXYLATE | | pteyear | | A | |
| 000814-49-3 | DIETHYL CHLOROPHOSPHATE (C4H10CLO3P) | | pteyear | | A | |
| 000067-64-1 | DIMETHYL KETONE | pteyear | | F | | |
| 000598-56-1 | ETHANAMINE,N,N-DIMETHYL- | | pteyear | | E | |
| 000071-55-6 | ETHANE, 1,1,1-TRICHLORO | pteyear | | Y | | |
| 000106-93-4 | ETHANE, 1,2-DIBROMO | pteyear | | Y | | |
| 000111-96-6 | ETHANE,1,1'-OXYBIS[-METHOXY] | | pteyear | | Y | |
| 000079-21-0 | ETHANEPEROXOIC ACID (METHYL ESTER) | | pteyear | | A | |
| 000075-08-1 | ETHANETHIOL | pteyear | | E | | |
| 000064-17-5 | ETHYL ALCOHOL (ETHANOL) | pteyear | | E | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 000110-71-4 | ETHYLENE GLYCOL DIMETHYL ETHER | pteyear | | Y | | |
| 000050-00-0 | FORMALDEHYDE | pteyear | Y | | | |
| 000068-12-2 | FORMAMIDE, N,N-DIMETHYL | pteyear | Y | | | |
| 000064-18-6 | FORMIC ACID | pteyear | B | | | |
| 000107-31-3 | FORMIC ACID, METHYL ESTER | pteyear | | E | | |
| 0NY100-00-0 | HAP | pteyear | | | | |
| 000110-54-3 | HEXANE | pteyear | Y | | | |
| 002525-62-4 | HEXANE, 1-ISOCYANATO | pteyear | A | | | |
| 000302-01-2 | HYDRAZINE | pteyear | Y | | | |
| 010035-10-6 | HYDROGEN BROMIDE | pteyear | B | | | |
| 007647-01-0 | HYDROGEN CHLORIDE | pteyear | | | | |
| 007722-84-1 | HYDROGEN PEROXIDE | pteyear | A | | | |
| 000543-27-1 | ISOBUTYL CHLORO FORMATE | pteyear | | A | | |
| 000067-63-0 | ISOPROPYL ALCOHOL | pteyear | E | | | |
| 004637-24-5 | METHANAMINE, 1,1'-DIMETHOXY,N,N' DIMETHYL | pteyear | | | | B |
| 000067-56-1 | METHYL ALCOHOL | pteyear | | | | |
| 000074-89-5 | METHYL AMINE | pteyear | B | | | |
| 000074-88-4 | METHYL IODIDE | pteyear | Y | | | |
| 001634-04-4 | METHYL TERTBUTYL ETHER | pteyear | | Y | | |
| 000121-44-8 | N,N-DIETHYL ETHANAMINE | pteyear | Y | | | |
| 0NY210-00-0 | OXIDES OF NITROGEN | pteyear | | | | |
| 0NY075-00-0 | PARTICULATES | pteyear | B | | | |
| 030414-53-0 | PENTANOIC ACID, 3-OXO-, METHYL ESTER | pteyear | | A | | |
| 000108-95-2 | PHENOL | pteyear | Y | | | |
| 010025-87-3 | PHOSPHORUS OXYCHLORIDE | pteyear | | C | | |
| 000762-04-9 | PHOSPORIC ACID, DIETHYL ESTER | pteyear | | A | | |
| 000682-30-4 | PHOSPORIC ACID, ETHENYL, DIETHYL ESTER | pteyear | | | | A |
| 0NY075-00-5 | PM-10 | pteyear | C | | | |
| 000108-18-9 | PROPANAMINE,N-(1-METHYLETHYL)-C5,H14,N2 | pteyear | | | | C |
| 000109-70-6 | PROPANE,1-BROMO-3-CHLORO- | pteyear | | A | | |
| 000108-59-8 | PROPANEDIOIC ACID, DIMETHYL ESTER | pteyear | | A | | |
| 000079-03-8 | PROPANOYL CHLORIDE | pteyear | C | | | |
| 002857-97-8 | SILANE, BROMOTRIMETHYL | pteyear | C | | | |
| 007446-09-5 | SULFUR DIOXIDE | pteyear | | | | |
| 000077-78-1 | SULFURIC ACID, DIMETHYL ESTER | pteyear | | Y | | |
| 000109-99-9 | TETRAHYDROFURAN | pteyear | E | | | |
| 000108-88-3 | TOLUENE | pteyear | Y | | | |
| 000079-01-6 | TRICHLOROETHYLENE | pteyear | Y | | | |
| 0NY998-00-0 | VOC | pteyear | | | | |
| 001330-20-7 | XYLENE, M, O & P MIXT. | pteyear | Y | | | |

## NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS

**Item A: Emergency Defense - 6NYCRR Part 201-1.5**

An emergency constitutes an affirmative defense to an action brought for noncompliance with emissions limitations or permit conditions for all facilities in New York State.

(a) The affirmative defense of emergency shall be demonstrated through properly signed, contemporaneous operating logs, or other relevant evidence that:

(1) An emergency occurred and that the facility owner and/or operator can identify the cause(s) of the emergency;
(2) The equipment at the permitted facility causing the emergency was at the time being properly operated;
(3) During the period of the emergency the facility owner and/or operator took all reasonable steps to minimize levels of emissions that exceeded the emission standards, or other requirements in the permit; and
(4) The facility owner and/or operator notified the Department within two working days after the event occurred. This notice must contain a description of the emergency, any steps taken to mitigate emissions, and corrective actions taken.

(b) In any enforcement proceeding, the facility owner and/or operator seeking to establish the occurrence of an emergency has the burden of proof.

(c) This provision is in addition to any emergency or upset provision contained in any applicable requirement.

**Item B: Public Access to Recordkeeping for Title V Facilities - 6NYCRR Part 201-1.10(b)**
The Department will make available to the public any permit application, compliance plan, permit, and monitoring and compliance certification report pursuant to Section 503(e) of the Act, except for information entitled to confidential treatment pursuant to 6NYCRR Part 616 - Public Access to records and Section 114(c) of the Act.

**Item C: Timely Application for the Renewal of Title V Permits - 6 NYCRR Part 201-6.3(a)(4)**
Owners and/or operators of facilities having an issued Title V permit shall submit a complete application at least 180 days, but not more than eighteen months, prior to the date of permit expiration for permit renewal purposes.

**Item D: Certification by a Responsible Official - 6 NYCRR Part**

**201-6.3(d)(12)**
Any application, form, report or compliance certification required to be submitted pursuant to the federally enforceable portions of this permit shall contain a certification of truth, accuracy and completeness by a responsible official. This certification shall state that based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

**Item E:** **Requirement to Comply With All Conditions - 6 NYCRR Part 201-6.5(a)(2)**
The permittee must comply with all conditions of the Title V facility permit. Any permit non-compliance constitutes a violation of the Act and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application.

**Item F:** **Permit Revocation, Modification, Reopening, Reissuance or Termination, and Associated Information Submission Requirements - 6 NYCRR Part 201-6.5(a)(3)**
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 permit condition.

**Item G:** **Cessation or Reduction of Permitted Activity Not a Defense - 6NYCRR Part 201-6.5(a)(5)**
It shall not be a defense for a permittee in an enforcement action to claim that a cessation or reduction in the permitted activity would have been necessary in order to maintain compliance with the conditions of this permit.

**Item H:** **Property Rights - 6 NYCRR Part 201-6.5(a)(6)**

This permit does not convey any property rights of any sort or any exclusive privilege.

**Item I:** **Severability - 6 NYCRR Part 201-6.5(a)(9)**

If any provisions, parts or conditions of this permit are found to be invalid or are the subject of a challenge, the remainder of this permit shall continue to be valid.

**Item J:** **Permit Shield - 6 NYCRR Part 201-6.5(g)**

All permittees granted a Title V facility permit shall be covered under the protection of a permit shield, except as provided under 6 NYCRR Subpart 201-6. Compliance with the conditions of the permit shall be deemed compliance with any applicable requirements as of the date of permit issuance, provided that such applicable requirements are included and are specifically identified in the permit, or the Department, in acting on the permit application or revision,

determines in writing that other requirements specifically identified are not applicable to the major stationary source, and the permit includes the determination or a concise summary thereof. Nothing herein shall preclude the Department from revising or revoking the permit pursuant to 6 NYCRR Part 621 or from exercising its summary abatement authority. Nothing in this permit shall alter or affect the following:

i. The ability of the Department to seek to bring suit on behalf of the State of New York, or the Administrator to seek to bring suit on behalf of the United States, to immediately restrain any person causing or contributing to pollution presenting an imminent and substantial endangerment to public health, welfare or the environment to stop the emission of air pollutants causing or contributing to such pollution;

ii. The liability of a permittee of the Title V facility for any violation of applicable requirements prior to or at the time of permit issuance;

iii. The applicable requirements of Title IV of the Act;

iv. The ability of the Department or the Administrator to obtain information from the permittee concerning the ability to enter, inspect and monitor the facility.

**Item K: Reopening for Cause - 6 NYCRR Part 201-6.5(i)**

This Title V permit shall be reopened and revised under any of the following circumstances:

i. If additional applicable requirements under the Act become applicable where this permit's remaining term is three or more years, a reopening shall be completed not later than 18 months after promulgation of the applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which this permit is due to expire, unless the original permit or any of its terms and conditions has been extended by the Department pursuant to the provisions of Part 201-6.7 and Part 621.

ii. The Department or the Administrator determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of the permit.

iii. The Department or the Administrator determines that the Title V permit must be revised or reopened to assure compliance with applicable requirements.

iv. If the permitted facility is an "affected source" subject to the requirements of Title IV of the Act, and additional requirements (including excess emissions requirements) become applicable. Upon approval by the Administrator, excess emissions offset plans shall be

deemed to be incorporated into the permit.

Proceedings to reopen and issue Title V facility permits shall follow the same procedures as apply to initial permit issuance but shall affect only those parts of the permit for which cause to reopen exists.

Reopenings shall not be initiated before a notice of such intent is provided to the facility by the Department at least thirty days in advance of the date that the permit is to be reopened, except that the Department may provide a shorter time period in the case of an emergency.

**Item L:** **Permit Exclusion - ECL 19-0305**

The issuance of this permit by the Department and the receipt thereof by the Applicant does not and shall not be construed as barring, diminishing, adjudicating or in any way affecting any legal, administrative or equitable rights or claims, actions, suits, causes of action or demands whatsoever that the Department may have against the Applicant for violations based on facts and circumstances alleged to have occurred or existed prior to the effective date of this permit, including, but not limited to, any enforcement action authorized pursuant to the provisions of applicable federal law, the Environmental Conservation Law of the State of New York (ECL) and Chapter III of the Official Compilation of the Codes, Rules and Regulations of the State of New York (NYCRR). The issuance of this permit also shall not in any way affect pending or future enforcement actions under the Clean Air Act brought by the United States or any person.

**Item M:** **Federally Enforceable Requirements - 40 CFR 70.6(b)**

All terms and conditions in this permit required by the Act or any applicable requirement, including any provisions designed to limit a facility's potential to emit, are enforceable by the Administrator and citizens under the Act. The Department has, in this permit, specifically designated any terms and conditions that are not required under the Act or under any of its applicable requirements as being enforceable under only state regulations.

**NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS**

Item A: **General Provisions for State Enforceable Permit Terms and Condition - 6 NYCRR Part 201-5**

Any person who owns and/or operates stationary sources shall operate and maintain all emission units and any required emission control devices in compliance with all applicable Parts of this Chapter and existing laws, and shall operate the facility in accordance with all criteria, emission limits, terms, conditions, and standards in this permit. Failure of such person to properly operate and maintain the effectiveness of such emission units and emission control devices may be sufficient reason for the Department to revoke or deny a permit.

The owner or operator of the permitted facility must maintain all

required records on-site for a period of five years and make them available to representatives of the Department upon request. Department representatives must be granted access to any facility regulated by this Subpart, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations or law.

**Regulatory Analysis**

| Location Facility/EU/EP/Process/ES | Regulation | Condition | Short Description |
|---|---|---|---|
| FACILITY | | 90 | Powers and Duties of the Department with respect to air pollution control |
| FACILITY | 40CFR 52-A.21(i)(2) | 32, 34, 38 | |
| 0-00001/-/01C | 40CFR 60-Dc.42c(d) | 58 | Standard for Sulfur Dioxide Firing Oil. (see narrative) |
| 0-00001 | 40CFR 60-Dc.42c(h) | 53 | Exemption from Averaging Requirements |
| 0-00001 | 40CFR 60-Dc.42c(i) | 54 | Standard for Sulfur Dioxide Period of Requirements. |
| 0-00001 | 40CFR 60-Dc.43c(d) | 55 | Time Period Requirements for Opacity |
| 0-00001/-/01C | 40CFR 60-Dc.48c(e) | 59 | Reporting and Recordkeeping Requirements. |
| 0-00001 | 40CFR 60-Dc.48c(g) | 56 | Reporting and Recordkeeping Requirements. |
| 0-00008 | 40CFR 60-Kb.116b(b) | 69 | NSPS for volatile organic liquid storage vessels-monitoring of operations |
| FACILITY | 40CFR 63-GGG.1250(a) | 31, 33, 34, 38, 39, 40 | Pharmaceutical NESHAP - Applicability of affected sources |
| 0-00013/00175 | 40CFR 63-GGG.1250(a) | 87, 88 | Pharmaceutical NESHAP - Applicability of affected sources |
| FACILITY | 40CFR 68 | 20 | Chemical accident prevention provisions |
| FACILITY | 40CFR 82-F | 21 | Protection of Stratospheric Ozone - recycling and emissions reduction |
| FACILITY | 6NYCRR 200.6 | 1, 22, 23, 24, 25 | Acceptable ambient air quality. |
| 0-00003/-/004/00399 | 6NYCRR 200.6 | 64 | Acceptable ambient air quality. |
| 0-00003/00019/006/00014 | 6NYCRR 200.6 | 66 | Acceptable ambient air quality. |
| 0-00009/00144 | 6NYCRR 200.6 | 82, 83, 84 | Acceptable ambient air quality. |
| 0-00013 | 6NYCRR 200.6 | 85 | Acceptable ambient air quality. |
| FACILITY | 6NYCRR 200.7 | 9 | |
| FACILITY | 6NYCRR 201-1.4 | 91 | Unavoidable noncompliance and violations |
| FACILITY | 6NYCRR 201-1.7 | 10 | |
| FACILITY | 6NYCRR 201-1.8 | 11 | Prohibition of reintroduction of collected contaminants to the air |
| FACILITY | 6NYCRR 201-3.2(a) | 12 | Exempt Activities - Proof |

| | | | |
|---|---|---|---|
| | | | of eligibility |
| FACILITY | 6NYCRR 201-3.3(a) | 13 | Trivial Activities - proof of eligibility |
| FACILITY | 6NYCRR 201-6 | 26, 51, 52 | Title V Permits and the Associated Permit Conditions |
| 0-00009 | 6NYCRR 201-6.5 | 70 | Standard Permit Requirements |
| FACILITY | 6NYCRR 201-6.5(a)(4) | 14 | |
| FACILITY | 6NYCRR 201-6.5(a)(7) | 2 | |
| FACILITY | 6NYCRR 201-6.5(a)(8) | 15 | |
| FACILITY | 6NYCRR 201-6.5(c) | 3 | Permit conditions for Recordkeeping and Reporting of Compliance Monitoring |
| FACILITY | 6NYCRR 201-6.5(c)(2) | 4 | Permit conditions for Recordkeeping and Reporting of Compliance Monitoring |
| FACILITY | 6NYCRR 201-6.5(c)(3)(ii) | 5 | Permit conditions for Recordkeeping and Reporting of Compliance Monitoring |
| FACILITY | 6NYCRR 201-6.5(d)(5) | 16 | |
| FACILITY | 6NYCRR 201-6.5(e) | 27 | |
| FACILITY | 6NYCRR 201-6.5(f) | 28 | |
| FACILITY | 6NYCRR 201-6.5(f)(6) | 17 | |
| FACILITY | 6NYCRR 201-7 | 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | Federally Enforceable Emissions Caps |
| 0-00009 | 6NYCRR 201-7 | 71 | Federally Enforceable Emissions Caps |
| 0-00013/00175 | 6NYCRR 201-7 | 87, 88, 89 | Federally Enforceable Emissions Caps |
| FACILITY | 6NYCRR 202-1.1 | 18 | |
| FACILITY | 6NYCRR 202-2.1 | 6 | Emission Statements - Applicability |
| FACILITY | 6NYCRR 202-2.5 | 7 | Emission Statements - record keeping requirements. |
| FACILITY | 6NYCRR 211.2 | 92 | General Prohibitions - air pollution prohibited. |
| FACILITY | 6NYCRR 211.3 | 19 | General Prohibitions - visible emissions limited |
| FACILITY | 6NYCRR 212.10 | 30, 33, 34, 35, 37, 38 | NOx and VOC RACT required at major facilities |
| 0-00009 | 6NYCRR 212.10 | 71 | NOx and VOC RACT required at major facilities |
| 0-00013/00175 | 6NYCRR 212.10 | 87 | NOx and VOC RACT required at major facilities |
| FACILITY | 6NYCRR 212.4(a) | 41, 42, 43, 44, 45, 46 | General Process Emission Sources - emissions from new sources and/or modifications |
| 0-00002 | 6NYCRR 212.4(a) | 60 | General Process Emission Sources - emissions from new sources and/or modifications |
| 0-00003/00019 | 6NYCRR 212.4(a) | 65 | General Process Emission Sources - emissions from new sources and/or modifications |
| 0-00009 | 6NYCRR 212.4(a) | 72, 73, 93, 94 | General Process Emission Sources - emissions from new sources and/or modifications |
| FACILITY | 6NYCRR 212.4(c) | 47 | General Process Emission Sources - emissions from new processes and/or |

| | | | |
|---|---|---|---|
| | | | modifications |
| FACILITY | 6NYCRR 212.5(f) | 48 | Applicable emission standards |
| FACILITY | 6NYCRR 212.6(a) | 49 | General Process Emission Sources - opacity of emissions limited |
| 0-00013 | 6NYCRR 212.6(a) | 86 | General Process Emission Sources - opacity of emissions limited |
| FACILITY | 6NYCRR 215 | 8 | |
| 0-00001/-/01C | 6NYCRR 227.2(b)(1) | 57 | |
| FACILITY | 6NYCRR 227-1.3(a) | 50 | Smoke Emission Limitations. |
| 0-00013/00175 | 6NYCRR 227-2 | 89 | Reasonably available control technology for NOx |
| FACILITY | 6NYCRR 227-2.1(a) | 34, 36, 38 | Further filtering of applicability |
| FACILITY | 6NYCRR 228.1 | 30, 33, 34, 35, 37, 38 | Permit requirments and applicability |
| 0-00009 | 6NYCRR 228.1 | 71 | Permit requirments and applicability |
| 0-00013/00175 | 6NYCRR 228.1 | 87 | Permit requirments and applicability |
| FACILITY | 6NYCRR 233.1(d)(4) | 30, 33, 34, 35, 37, 38 | Applicability and compliance. |
| 0-00009 | 6NYCRR 233.1(d)(4) | 71 | Applicability and compliance. |
| 0-00009 | 6NYCRR 233.3(a)(1) | 74, 75, 76, 77, 78 | Process equipment requirements |
| 0-00002 | 6NYCRR 233.3(b)(2) | 61 | Air dryer and production equipment exhaust system requirements |
| 0-00008 | 6NYCRR 233.3(d) | 67 | |
| 0-00002 | 6NYCRR 233.3(f) | 62 | In-process tank requirements |
| 0-00009 | 6NYCRR 233.3(f) | 79 | In-process tank requirements |
| 0-00009 | 6NYCRR 233.5(a) | 80 | |
| 0-00002 | 6NYCRR 233.5(b) | 63 | |
| 0-00008 | 6NYCRR 233.5(b) | 68 | |
| 0-00009 | 6NYCRR 233.5(b) | 81 | |

**Applicability Discussion:**

Mandatory Requirements: The following facility-wide regulations are included in all Title V permits:

ECL 19-301.
This section of the Environmental Conservation Law establishes the powers and duties assigned to the Department with regard to administering the air pollution control program for New York State.

6NYCRR Part 200-.6
Acceptable ambient air quality - prohibits contravention of ambient air quality standards without mitigating measures

6NYCRR Part 200-.7
Anyone owning or operating an air contamination source which is equipped with an emission control device must operate the control consistent with ordinary and necessary practices, standards and procedures, as per manufacturer's specifications and keep it in a satisfactory state of maintenance and repair so that it operates effectively

6NYCRR Part 201-1.4
This regulation specifies the actions and recordkeeping and reporting requirements for any violation of an applicable state enforceable emission standard that results from a necessary scheduled equipment maintenance, start-up, shutdown, malfunction or upset in the event that these are unavoidable.

6NYCRR Part 201-1.7
Requires the recycle and salvage of collected air contaminants where practical

6NYCRR Part 201-1.8
Prohibits the reintroduction of collected air contaminants to the outside air

6NYCRR Part 201-3.2(a)
An owner and/or operator of an exempt emission source or unit may be required to certify that it operates within the specific criteria described in this Subpart.
All required records must be maintained on-site for a period of 5 years and made available to department representatives upon request. In addition, department representatives must be granted access to any facility which contains exempt emission sources or units, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations, or law.

6NYCRR Part 201-3.3(a)
The owner and/or operator of a trivial emission source or unit may be required to certify that it operates within the specific criteria described in this Subpart. All required records must be maintained on-site for a period of 5 years and made available to department representatives upon request. In addition, department representatives must be granted access to any facility which contains trivial emission sources or units subject to this Subpart, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations, or law.

6NYCRR Part 201-6
This regulation applies to those terms and conditions which are subject to Title V permitting. It establishes the applicability criteria for Title V permits, the information to be included in all Title V permit applications as well as the permit content and terms of permit issuance. This rule also specifies the compliance, monitoring, recordkeeping, reporting, fee, and procedural requirements that need to be met to obtain a Title V permit, modify the permit and demonstrate conformity with applicable requirements as listed in the Title V permit. For permitting purposes, this rule specifies the need to identify and describe all emission units, processes and products in the permit application as well as providing the Department the authority to include this and any other information that it deems necessary to determine the compliance status of the facility.

6NYCRR 201-6.5(a)(4)
This mandatory requirement applies to all Title V facilities. It requires the permittee to provide information that the Department may request in writing, within a reasonable time, in order to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. The request may include copies of records required to be kept by the

permit.

6NYCRR 201-6.5(a)(7)
This is a mandatory condition that requires the owner or operator of a facility subject to Title V requirements to pay all applicable fees associated with the emissions from their facility.

6NYCRR 201-6.5(a)(8)
This is a mandatory condition for all facilities subject to Title V requirements. It allows the Department to inspect the facility to determine compliance with this permit, including copying records, sampling and monitoring, as necessary.

6NYCRR Part 201-6.5(c)
This requirement specifies, in general terms, what information must be contained in any required compliance monitoring records and reports. This includes the date, time and place of any sampling, measurements and analyses; who performed the analyses; analytical techniques and methods used as well as any required QA/QC procedures; results of the analyses; the operating conditions at the time of sampling or measurement and the identification of any permit deviations. All such reports must also be certified by the designated responsible official of the facility.

6NYCRR Part 201-6.5(c)(2)
This requirement specifies that all compliance monitoring and recordkeeping is to be conducted according to the terms and conditions of the permit and follow all QA requirements found in applicable regulations. It also requires monitoring records and supporting information to be retained for at least 5 years from the time of sampling, measurement, report or application. Support information is defined as including all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by the permit.

6NYCRR Part 201-6.5(c)(3)(ii)
This regulation specifies any reporting requirements incorporated into the permit must include provisions regarding the notification and reporting of permit deviations and incidences of noncompliance stating the probable cause of such deviations, and any corrective actions or preventive measures taken.

6NYCRR 201-6.5(d)(5)
This condition applies to every Title V facility subject to a compliance schedule. It requires that reports, detailing the status of progress on achieving compliance with emission standards, be submitted semiannually.

6NYCRR Part 201-6.5(e)
Sets forth the general requirements for compliance certification content; specifies an annual submittal frequency; and identifies the EPA and appropriate regional office address where the reports are to be sent.

6NYCRR 201-6.5(f)(6)
This condition allows changes to be made at the facility, without modifying the permit, provided the changes do not cause an emission limit contained in this permit to be exceeded. The owner or operator of the facility must notify the Department of the change. It is applicable to all Title V permits which may be subject to an off permit change.

6NYCRR Part 202-1.1
This regulation allows the department the discretion to require an emission test for the purpose of determining compliance. Furthermore, the cost of the test, including the preparation of the report are to be borne by the owner/operator of the source.

6NYCRR Part 202-2.1
Requires that emission statements shall be submitted on or before April 15th each year for emissions of the previous calendar year.

6NYCRR Part 202-2.5
This rule specifies that each facility required to submit an emission statement must retain a copy of the statement and supporting documentation for at least 5 years and must make the information available to department representatives.

6NYCRR Part 211-.2
This regulation prohibits any emissions of air contaminants to the outdoor atmosphere which may be detrimental to human, plant or animal life or to property, or which unreasonably interferes with the comfortable enjoyment of life or property regardless of the existence of any specific air quality standard or emission limit.

6 NYCRR Part 211.3
This condition requires that the opacity (i.e., the degree to which emissions other than water reduce the transmission of light) of the emissions from any air contamination source be less than 20 percent (six minute average) except for one continuous six-minute period per hour of not more than 57 percent.

6 NYCRR Part 215
Prohibits open fires at industrial and commercial sites.

40 CFR Part 68.
This Part lists the regulated substances and there applicability thresholds and sets the requirements for stationary sources concerning the prevention of accidental releases of these substances.

40 CFR Part 82, Subpart F
Subpart F requires the reduction of emissions of class I and class II refrigerants to the lowest achievable level during the service, maintenance, repair, and disposal of appliances in accordance with section 608 of the Clean Air Act Amendments of 1990. This subpart applies to any person servicing, maintaining, or repairing appliances except for motor vehicle air conditioners. It also applies to persons disposing of appliances, including motor vehicle air conditioners, refrigerant reclaimers, appliance owners, and manufacturers of appliances and recycling and recovery equipment. Those individuals, operations, or activities affected by this rule, may be required to comply with specified disposal, recycling, or recovery practices, leak repair practices, recordkeeping and/or technician certification requirements.

**Facility Specific Requirements**
In addition to Title V, WYETH PHARMACEUTICALS has been determined to be subject to the following regulations:

40CFR 52-A.21 (i) (2)
Any stationary source or modification to which the requirements of this regulation apply cannot begin construction without a valid permit.

Emissions of Nitrogen Oxides (NOx) and Sulfur Dioxide (SO2) from the facility are capped at 99 tons per year. Therefore, the control requirements contained in 40 CFR 52, Federal Prevention of Significant Deterioration of Air Quality (PSD) do not presently apply to sources at the facility.

40CFR 60-Dc.42c (d)
This regulation requires that on or after the date on which the initial performance test is completed or required to be completed under section 60.8 of 40 CFR 60 Subpart A, no owner or operator of an affected facility that combusts oil, shall combust oil with a sulfur content in excess of 0.5 percent by weight.

40CFR 60-Dc.42c (h)
This regulation requires that compliance with emission limits and/or fuel oil sulfur limitations be based on a certification from the fuel supplier as stated in paragraph 40 CFR 60-Dc.48c(f)(1), (2), or (3) as applicable

40CFR 60-Dc.42c (i)
This regulation requires that the sulfur dioxide emission limits, percentage reductions, and fuel oil sulfur limitations apply at all times, including periods of startup, shutdown, and malfunction.

40CFR 60-Dc.43c (d)
This regulation requires that the particulate matter and opacity standards of section 40 CFR 60-Dc.43c apply at all times, except during periods of startup, shutdown, and malfunction.

## 40CFR 60-Dc.48c (e)
The owner or operator of each affected facility subject to fuel sulfur limits under section 60.43c shall keep records and submit reports as required under paragraph (d) of this section, including information contained in this paragraph, as applicable.

40CFR 60-Dc.48c (g)
The owner or operator of each affected facility shall record and maintain records of the amount of each fuel combusted during each day.

40CFR 60-Kb.116b (b)
Owners or operators of affected storage tanks with capacities greater than or equal to 10,000 gallons must keep records of the tanks dimensions and an analysis of its capacity for the life of the tank. If the tank's capacity is less than 20,000 gallons, then it is subject to no other provisions of this subpart.

40CFR 63-GGG.1250 (a)
This requirement specifies whether the facility is subject to the Pharmaceutical NESHAP (40CFR63, Subpart GGG). The facility is subject if a pharmaceutical product is manufactured there, the entire plant is a major source of hazardous air pollutant (HAP) emissions, and the part of the plant producing the pharmaceutical product either processes, uses, or produces a HAP.

This facility is not subject to this requirement because total and individual HAP emissions are capped below major source thresholds.

6NYCRR 201-6.5

This section of the Title V permitting requirements details the following information: general conditions; permit conditions for monitoring, recordkeeping and reporting of compliance monitoring; compliance certification; operational flexibility; permit shield; term of permits; and reopening for cause.

6NYCRR 201-6.5 (f)
This regulation defines in general terms under what circumstances changes would be allowed without a permit modification provided the permit contains sufficient operational flexibility provisions.

6NYCRR 201-7
This regulation sets forth an emission cap that cannot be exceeded by the facility. In this permit that cap is for VOCs, HAPs, SO2 and NOx.

Emissions of Nitrogen Oxides (NOx) and Sulfur Dioxide (SO2) from the facility are each capped at 99 tons per year. Therefore, the control requirements contained in 6 NYCRR Subpart 227-2, Reasonably Available Control Technology (RACT) for NOx, and 40 CFR 52, Federal Prevention of Significant Deterioration of Air Quality (PSD) do not presently apply to sources at the facility. In addition, emissions of Volatile Organic Compounds (VOC's) from the facility are capped at 49 tons per year, such that the VOC RACT provisions of 6 NYCRR Section 212.10, as well as VOC RACT provisions in other rules (e.g., 6 NYCRR Parts 228 and 233) which are triggered by a facility-wide Potential To Emit (PTE) VOC's over 50 tons per year do not apply. They are still, however, subject to certain VOC RACT requirements triggered when the facility's PTE for VOC's is over 10 tons per year. Facility-wide total and individual HAP emissions are capped below 24.5 and 9.5 tons per year, respectively. This caps the facility out of 40 CFR 62-GGG.1250(a), National Emission Standards for Hazardous Pollutants (NESHAP) for Pharmaceuticals Production. Finally, through particulate emission limits control efficiencies set on each process emission point, a preventative maintenance requirement on all particulate control devices and boiler fuel use limitations resulting from the above NOx and SO2 emission limits, the facility's potential to emit particulate matter less than 10 microns in diameter (PM-10) is less than the 100 tpy major source threshold.

6NYCRR 212 .10
Emissions of Volatile Organic Compounds (VOC's) from the facility are capped at 49 tons per year, such that the VOC RACT provisions of 6 NYCRR Section 212.10 does not apply.

6NYCRR 212 .4 (a)
This rule requires compliance with the degree of control specified in Tables 2, 3 and 4 for new (after July 1, 1973) process emission sources.

6NYCRR 212 .4 (c)
This rule requires existing sources (in operation after July 1, 1973) of solid particulates with environmental rating of B or C which are not subject to Table 5 "Processes for which Permissible Emission Rate is Based on Process Weight, to be limited to an particulate emission rate not to exceed 0.05 grains per dry standard cubic foot.

6NYCRR 212 .5 (f)
Owners and/or operators that have established annual emission limits to satisfy other requirements must continue to meet these other requirements.

6NYCRR 212 .6 (a)
This rule specifies an opacity limitation of less than 20% for any six consecutive minute period for all process emission sources.

6NYCRR 227 .2 (b) (1)
This regulation is from the 1972 version of Part 227 and still remains as part of New York's SIP. The rule establishes a particulate limit of 0.10 lbs/mmBtu based on a 2 hour average emission for any oil fired stationary combustion installation.

6NYCRR 227-1.3 (a)
This regulation prohibits any person from operating a stationary combustion installation which emits smoke equal to or greater than 20% opacity except for one six-minute period per hour of not more than 27% opacity.

6NYCRR 227-2
This regulation limits the emission of oxides of nitrogen (NOx) from stationary combustion installations (boilers, combustion turbines and internal combustion engines).

Emissions of Nitrogen Oxides (NOx) from the facility are capped at 99 tons per year. Therefore, the control requirements contained in 6 NYCRR Subpart 227-2, Reasonably Available Control Technology (RACT) for NOx do not presently apply to sources at the facility.

6NYCRR 227-2.1 (a)
This requirement notes that a facility is subject to the reasonably available control technology (RACT) for oxides of nitrogen (NOx).

Emissions of Nitrogen Oxides (NOx) from the facility are capped at 99 tons per year. Therefore, the control requirements contained in 6 NYCRR Subpart 227-2, Reasonably Available Control Technology (RACT) for NOx do not presently apply to sources at the facility.

6NYCRR 228 .1
Emissions of Volatile Organic Compounds (VOC's) from this facility are capped at 49 tons per year, such that the VOC RACT provisions of 6 NYCRR Section 228.1 which are triggered by a facility-wide Potential To Emit (PTE) VOC's over 50 tons per year do not apply. They are still, however, subject to certain VOC RACT requirements triggered when the facility's PTE for VOC's is over 10 tons per year.

6NYCRR 233 .1 (d) (4)
This requirement details which facilities outside of the New York City Metropolitan area and Lower Orange County Metropolitan area are subject to the Pharmaceutical and Cosmetic Manufacturing Processes rule (6NYCRR, Part 233) and when they must be in compliance with the rule.

This requirement applies to all cosmetic manufacturing processes and all non-synthesized pharmaceutical manufacturing processes at facilities with a high potential to emit volatile organic compounds (at least 50 tons per year).

Emissions of Volatile Organic Compounds (VOC's) from the facility are capped at 49 tons per year, such that the VOC RACT provisions of 6 NYCRR Section 233.1 (d) (4) which are triggered by a facility-wide Potential To Emit (PTE) VOC's over 50 tons per year do not apply.

6NYCRR 233 .3 (a) (1)
This condition reduces the emissions of volatile organic compounds from pharmaceutical and cosmetic manufacturing facilities by regulating the temperature at the outlet of condensers. This condition refers certain manufacturing equipment to a table when a condenser is used to control the emissions from these pieces of equipment. The condition then specifies a certain temperature at the outlet from the condenser according to the vapor pressure of the volatile organic compound passing through it.

6NYCRR 233 .3 (b) (2)
This condition reduces the emissions of volatile organic compounds (VOC's) from pharmaceutical and cosmetic manufacturing facilities by setting a daily emission limit of VOC's from air dryers and production equipment exhaust systems of 33 pounds/day, if the emission rate potential is low.

6NYCRR 233 .3 (d)
This condition reduces the fugitive releases of volatile organic compounds (VOC's) by requiring that all storage tanks storing VOC's with a high vapor pressure be equipped with conservation vents that trap the chemicals inside.

6NYCRR 233 .3 (f)
This condition reduces the emissions of volatile organic compounds (VOC's) by requiring that all in-process tanks containing VOC's have covers on the openings except when an operator needs to access the inside of them.

6NYCRR 233 .5 (a)
This condition requires the facility that is subject to the Pharmaceutical and Cosmetic Manufacturing Processes rule (6NYCRR, Part 233) to keep records pertaining to the vapor pressure(s) of the volatile organic compound(s) being controlled for every process subject to this rule. Certain parameters regarding the operation of control equipment used to control the emissions of VOC's from processes that are subject to this rule must also be recorded. These records must be kept for at least five years.

6NYCRR 233 .5 (b)
This condition requires the facility to record certain information on any leaks of volatile organic compounds found on equipment involved in the manufacture of pharmaceutical or cosmetic products subject to 6NYCRR, Part 233. This information includes an identification of the leaking equipment, the date and time of the leak, the action taken to repair the leak, and the date and time of the repair. These records must be kept for five years.

**Compliance Certification**
Summary of monitoring activities at WYETH PHARMACEUTICALS:

| Location Facility/EU/EP/Process/ES | Cond No. | Type of Monitoring |
|---|---|---|
| 0-00001/-/01C | 58 | work practice involving specific operations |
| 0-00001/-/01C | 59 | record keeping/maintenance procedures |
| 0-00001 | 56 | record keeping/maintenance procedures |
| 0-00008 | 69 | record keeping/maintenance procedures |
| FACILITY | 22 | record keeping/maintenance procedures |
| FACILITY | 23 | record keeping/maintenance procedures |
| FACILITY | 24 | record keeping/maintenance procedures |
| FACILITY | 25 | record keeping/maintenance procedures |
| 0-00003/-/004/00399 | 64 | work practice involving specific operations |
| 0-00003/00019/006/00014 | 66 | work practice involving specific operations |
| 0-00009/00144 | 82 | record keeping/maintenance procedures |
| 0-00009/00144 | 83 | monitoring of process or control device parameters as surrogate |
| 0-00009/00144 | 84 | monitoring of process or control device parameters as surrogate |
| 0-00013 | 85 | record keeping/maintenance procedures |
| 0-00009 | 70 | record keeping/maintenance procedures |
| FACILITY | 5 | record keeping/maintenance procedures |

| | | |
|---|---|---|
| FACILITY | 27 | record keeping/maintenance procedures |
| FACILITY | 28 | record keeping/maintenance procedures |
| FACILITY | 30 | intermittent emission testing |
| FACILITY | 31 | monitoring of process or control device parameters as surrogate |
| FACILITY | 32 | record keeping/maintenance procedures |
| FACILITY | 33 | monitoring of process or control device parameters as surrogate |
| FACILITY | 34 | record keeping/maintenance procedures |
| FACILITY | 35 | record keeping/maintenance procedures |
| FACILITY | 36 | record keeping/maintenance procedures |
| FACILITY | 37 | record keeping/maintenance procedures |
| FACILITY | 38 | record keeping/maintenance procedures |
| FACILITY | 39 | monitoring of process or control device parameters as surrogate |
| FACILITY | 40 | record keeping/maintenance procedures |
| 0-00009 | 71 | record keeping/maintenance procedures |
| 0-00013/00175 | 87 | intermittent emission testing |
| 0-00013/00175 | 88 | intermittent emission testing |
| 0-00013/00175 | 89 | intermittent emission testing |
| FACILITY | 6 | record keeping/maintenance procedures |
| FACILITY | 41 | record keeping/maintenance procedures |
| FACILITY | 42 | intermittent emission testing |
| FACILITY | 43 | monitoring of process or control device parameters as surrogate |
| FACILITY | 44 | intermittent emission testing |
| FACILITY | 45 | record keeping/maintenance procedures |
| FACILITY | 46 | monitoring of process or control device parameters as surrogate |
| 0-00003/00019 | 65 | intermittent emission testing |
| 0-00009 | 72 | record keeping/maintenance procedures |
| 0-00009 | 73 | monitoring of process or control device parameters as surrogate |
| 0-00009 | 93 | record keeping/maintenance procedures |
| 0-00009 | 94 | monitoring of process or control device parameters as surrogate |
| FACILITY | 47 | record keeping/maintenance procedures |
| FACILITY | 49 | monitoring of process or control device parameters as surrogate |
| 0-00013 | 86 | monitoring of process or control device parameters as surrogate |
| 0-00001/-/01C | 57 | intermittent emission testing |
| FACILITY | 50 | monitoring of process or control device parameters as surrogate |
| 0-00009 | 74 | monitoring of process or control device parameters as surrogate |

| | | |
|---|---|---|
| 0-00009 | 75 | monitoring of process or control device parameters as surrogate |
| 0-00009 | 76 | monitoring of process or control device parameters as surrogate |
| 0-00009 | 77 | monitoring of process or control device parameters as surrogate |
| 0-00009 | 78 | monitoring of process or control device parameters as surrogate |
| 0-00002 | 61 | record keeping/maintenance procedures |
| 0-00008 | 67 | record keeping/maintenance procedures |
| 0-00002 | 62 | record keeping/maintenance procedures |
| 0-00009 | 79 | record keeping/maintenance procedures |
| 0-00009 | 80 | record keeping/maintenance procedures |
| 0-00002 | 63 | record keeping/maintenance procedures |
| 0-00008 | 68 | record keeping/maintenance procedures |
| 0-00009 | 81 | record keeping/maintenance procedures |

**Basis for Monitoring**

6NYCRR 200.6 - Prohibition of Simultaneous Operation of Processes Using Boron Trichloride (a.k.a., Borane, Trichloro), Bromine or Chloroform

Because of high projected short-term ambient impacts, simultaneous operation of processes using Boron Trichloride (a.k.a., Borane, Trichloro), Bromine or Chloroform are prohibited. Such processes are run very infrequently, and the likelihood that the source owner would need to run more than one of these processes at a time is low. Therefore, the source owner is simply being required to maintain a record of each run, including the time period during which it was run in order to document compliance with this prohibition.

6NYCRR 200.6 - Operation/Maintenance of PM-10 Controls

If uncontrolled, emissions of particulate matter less than 10 microns in diameter (i.e., PM-10) from the emission sources at this facility could create excessive ambient impacts. Most of these sources, however, are equipped with control devices to capture PM-10 before it can be emitted. This condition requires Wyeth to operate such control devices whenever they operate the corresponding process. It also requires them to maintain the devices in accordance with manufacturer's specifications so that the device will operate effectively. The frequency of such maintenance should be identified in the manufacturer's specification. If not, then the condition specifies a minimum semi-annual frequency. Since most of these control devices are relatively simple filters, and not prone to frequent malfunctions, semi-annual maintenance is believed to be sufficient to prevent excessive ambient impacts from occurring. In addition, this monitoring activity along with others contained in the permit provide reasonable assurance of compliance with 6NCYRR Part 212 opacity and particulate limits.

6NYCRR 200.6 - Limit On Benzene Content of Mineral Spirits (Facility-wide)

This monitoring condition has been included to limit the potential for adverse ambient impacts (concentrations) from emissions of benzene. While benzene is not specifically used in these sources, the mineral spirits used may contain small amounts of benzene. This condition requires that the supplier of the mineral spirits certify that this benzene content is below 0.1 percent by weight. Since there is no reason to believe that the benzene

content will change while using the same certified product, the monitoring frequency of once per raw material change is justified.

6NYCRR 201-7, 6NYCRR 212.10, 6NYCRR 227-2.1(a) and 40CFR 52.21(i)(2) - VOC, NOx and SO2 Emissions Capped

Emissions of Volatile Organic Compounds (VOC's), Oxides of Nitrogen (NOx) and Sulfur Dioxide (SO2) from this facility have been capped at 49, 99 and 99 tons per year, respectively. In the case of VOC emissions, this renders non-applicable most of the Reasonably Available Control Technology (RACT) requirements contained in 6 NYCRR Parts 212, 228 and 233 that might otherwise apply. Similarly, in the case of NOx, the RACT requirements contained in 6 NYCRR Part 212 and Subpart 227-2 are rendered non-applicable. Finally, SO2 emissions are capped such that federal Prevention of Significant Deterioration of Air Quality requirements, under 40 CFR 52 are not triggered.

The premise is that Wyeth will calculate, on a monthly basis, the facility-wide emissions of each of these contaminants, based upon production, hours of operations and fuel usage information kept at the facility. Each month, they will also calculate the total emissions of each contaminant for the preceding twelve months such that compliance with their annual caps can be monitored on a monthly basis. This enables them to determine whether they are approaching any of their annual limits and to what extent they must adjust production levels in order to remain in compliance.

6NYCRR 201-7, 40CFR 63 Subpart GGG - Individual and Total HAP Caps

Emissions of individual and total Hazardous Air Pollutants (HAPs) from this facility are capped at 9.5 and 49.5 tons per year, respectively. The caps limit emissions of HAPs (both individual and total) from the facility such that requirements contained in the subject NESHAP do not apply. The various capping conditions also serve to limit the potential for adverse ambient impacts from these sources.

The premise is that Wyeth will calculate, on a monthly basis, the facility-wide emissions of each of these contaminants, based upon production information kept at the facility. Each month, they will also calculate the total emissions of each contaminant for the preceding twelve months such that compliance with their annual caps can be monitored on a monthly basis. This enables them to determine whether they are approaching any of their annual limits and to what extent they must adjust production levels in order to remain in compliance.

6NYCRR 201-7 - Requirement to Test RTO/Scrubber System for Control Efficiency (EU 0-00013: EP 00175)

These conditions require that the subject emission point be stack tested to determine compliance with the methylene chloride, methyl alcohol, hydrogen chloride and VOC limits specified. These limits have been established to cap VOC and HAP emissions, as well as to limit the potential for adverse ambient impacts (concentrations) from emissions of these contaminants. The data gathered during once per term testing will help to refine the limits on the control system's oxidizer combustion temperatures, as well as scrubber liquid pH and flow rates set forth in other conditions in this permit. Based on these limits, compliance will be monitored on a regular basis through these other conditions.

6NYCRR 201-7 - VOC Control Efficiency Limit (EU 0-00006: ES 00152, 00231)

These conditions require that the emission sources specified be stack tested to determine compliance with the control efficiency limits specified for VOCs. Since compliance with the facility-wide VOC cap depends in part on the control efficiencies achieved by these devices, it is important that these are verified. The data gathered during once per term testing will help to refine the limits on the scrubbers and set forth in other conditions in

this permit. Based on these limits, compliance will be monitored on a regular basis through other conditions.

6NYCRR 212.4(a) - "Active" Particulate Emission Limit

These monitoring conditions have been included to address the emission control requirements, contained in this rule, for A-rated particulate matter. The applicable control requirements for these sources is 99% or greater or BACT and are identified in the permit. The specific limit is based on emission rate potentials and approved air dispersion model impacts of facility-wide mass emission rates, estimated by the facility. These predicted impacts were reviewed against an annual guideline concentration (AGC), specifically developed, for the types of active particulate potentially released from this facility. These emissions are controlled by basically two types of control devices, High Efficiency Particle Air (HEPA) filters and dust collectors.

HEPA filters achieving a minimum of 99.97 % control of particles 0.3 micron or less are considered BACT for these sources. Since the high degree of control achieved by HEPA filters reduces emission below applicable stack test Method 5 detection levels, compliance will be verified through manufacturer's certification of control efficiency and recommended maximum pressure drop across the filter. In addition, the owner or operator is required to continuously monitor and record the pressure drop across the filter, at specific intervals, to demonstrate continuous compliance.

Dust collectors shall be stack tested to verify particulate control efficiencies. If this is prohibited by test method detection levels, the owner or operator shall use an alternate method to demonstrate compliance to the Department's satisfaction. Compliance assurance for these sources will be provided through daily visible emission observations. Since these control devices have a potential to emit A-rated particulate, any visible emissions observed will require immediate corrective measures.

6NYCRR 212.4(c) - Particulate Grain Loading Limit (EU 0-000002, 00003, 00004, 00005, 00006, 00013)

This condition requires stack testing of emission points with B & C - rated particulates to determine compliance with the particulate matter limit of 0.05 grains/dry standard cubic foot of exhaust gas at the Department's descretion. The monitoring frequency is justified by the fact that these sources are either very minor sources and/or have good particulate emission control equipment for which regular maintenance is required via another permit condition. In addition, reasonable compliance assurance is provided through verification of pertinent information relating to particulate emissions of the source, including but not limited to, production rate, process material, air flow rate, control equipment parameters, visible emissions observations and etc.

6NYCRR 212.6(a) - Opacity Limit on Process Emission Sources (EU Nos. 0-00002, 0-00003, 0-00004, 0-00005, 0-00006,and 0-00013)

The rule does not specify any monitoring frequency, so with the exception of EP 00175, in EU 00013, the requirement is to evaluate opacity based on results of weekly visible emission observations. Due to the number of sources at this facility that potentially emit particulate matter, and the fact that most are either well controlled or very minor sources of PM, it was determined that more frequent monitoring was unnecessary and excessively burdensome. The condition associated with EP 00175 requires that a visible emissions evaluation be performed if a problem is suspected, based upon any unusual operational parameters (e.g., pressure drop across filters, etc.). This is because failure of these PM controls could result in problems with the hazardous air pollutant (HAP) and VOC control systems downstream. Therefore, they need to be monitored more intensively.

6NYCRR 227-1.3(a) - Monitoring of Opacity from Combustion Sources

This monitoring condition has been included to address the visible emissions requirements of 6 NYCRR,

Subpart 227-1. The boilers at this facility primarily burn natural gas and are expected to emit virtually no visible emissions under normal operating conditions. Other stationary combustion sources (e.g., emergency diesel generators, space heaters, etc.) are generally operated on a regular, but infrequent, basis or are very minor sources. The rule does not specify any monitoring frequency. Based upon the factors noted above, however, a daily monitoring frequency is justified.

6NYCRR 227.2 (b)(1) - Particulate Emissions Limit from Any Oil Fired Stationary Combustion Installation

The facility uses natural gas under typical operation with No. 2 fuel oil as backup due to interruptable service or maintenance of system. This PM requirement applies only to sources which combust fuel oil. Since, the facility's intention is to combust only natural gas, except during unusual events, it seems reasonable to establish the monitoring frequency based on usage of a minimal amount of No. 2 fuel oil, or at the request of a regulatory agency. In addition, these sources are observed daily for visible emissions. Any visible emissons would require the facility investigate the situation and ensure good combustion.

6NYCRR 40CFR 60.42c(d) - Fuel Oil Sulfur Content Limitation

This condition assures compliance with the 0.5% sulfur content requirement contained in 40CFR 60.42c(d) which applies to three of the four boilers and the 1.5% sulfur content requirement from 6NYCRR 225-1 which applies to all four boilers used at the facility. This requirement is part of the monitoring needed to ensure compliance with the SO2 emissions cap, established to prevent the facility from becoming subject to federal Prevention of Significant Deterioration of Air Quality requirements, under 40 CFR 52. The emission factor specified for use in calculating SO2 emissions assumes a maximum fuel oil sulfur content of 0.5% by weight, and this condition requires that this be certified by the supplier of the fuel. Since the fuel burned at this facility in recent years has been primarily natural gas, and oil usage has been very low, the semi-annual reporting frequency is considered to be sufficient for compliance assurance.

40CFR 60.48c(g), Subpart Dc - Monitoring of Fuel Combusted

This monitoring condition has been included because this rule mandates that the source owner record and maintain records of the amounts of each fuel combusted during each day. The requirement applies to three of the four boilers permitted at this facility.

6NYCRR 233.3(b)(2) - Daily VOC Limit on Synthesized Pharmaceutical Manufacturing Process Exhausts (EU 0-00002)

This requires that calculations be performed daily to determine the emissions of volatile organic compounds (VOCs) for that day from specified process equipment. The requirement is that the VOC emissions from these process exhausts be no greater than 33 pounds per day. This only applies to "synthesized pharmaceutical manufacturing processes" involving air dryers or production equipment exhaust systems, and excludes those performed to produce products for study rather than eventual sale. In addition, the facility is capped out of Part 233 requirements with respect to other pharmaceutical manufacturing processes. Therefore, the number of processes involved is relatively small. Due primarily to the small number of subject processes and their batch-wise nature, the use of accepted chemical process calculations, performed daily, to demonstrate compliance with this requirement is justified.

6NYCRR 233.3(f) - In-Process Tanks Containing VOC (EU Nos. 0-00002 & 0-00009)

This monitoring condition has been included because this rule requires that in-process tanks containing a VOC be covered unless production, sampling, maintenance, or inspection procedures require operator access. This

shall be monitored at least once per batch run and/or each time the raw material(s) contained in the tank(s) is(are) changed. Once again, this requirement applies only to a small number of situations as a result of the facility VOC emissions being capped below 50 tons per year. The monitoring frequency is justified by the fact that the rule does not specify any monitoring frequency and the batch-wise nature of the processes performed. It makes sense to check that the tanks are covered each time that the equipment is used for a different batch or raw material.

6NYCRR 233.5(b) - Leaking Equipment (EU Nos. 0-00002, 0-00008 & 0-00009)

This monitoring requirement has been included to address the equipment leak requirements of Part 233. This shall be monitored at least once per batch for the process equipment covered by EU Nos. 0-00002 and 0-00009 and daily for the storage tanks covered by EU No. 0-00008. Again, this requirement applies only to a small number of situations involving the process equipment as a result of the facility VOC emissions being capped below 50 tons per year. Due to the fact that the storage tanks serve equipment used for both applicable and non-applicable processes, they must meet the requirement all of the time. The monitoring frequency of once per batch for process equipment is justified by the fact that the rule does not specify any monitoring frequency and the batch-wise nature of the processes performed. If checked once during each batch, any leaks detected can then be repaired before beginning the next. The daily monitoring frequency specified for storage tanks is justified since their use may not be tied exclusively to a single process or the production of a single batch of material, yet it allows for the discovery and repair of a leak within a reasonable time period.

6NYCRR 233.3(d) - Conservation Vents Required on Solvent Storage Tanks (EU 0-00008)

This condition reduces the fugitive releases of volatile organic compounds (VOC's) by requiring that all storage tanks storing VOC's with a high vapor pressure be equipped with conservation vents that trap the chemicals inside. It requires that the vents be inspected and maintained per the manufacturer's specifications on a quarterly basis. Conservation vents are relatively simple devices. Once installed, they should be pretty reliable. Quarterly inspection/maintenance should provide for little chance of a long-term release due to failure of the device.

6NYCRR 212.4(a) - Methylene Chloride Emission Limit (EU 0-00003: EP 00019)

This requires that the emission points specified be stack tested, at the request of the Department, to determine compliance with the methylene chloride emission limits established under Table 2 in this rule. The emission rates have been calculated using conservative chemical process calculations, and represent worst-case emission situations. In addition, there are no control devices employed for methylene chloride emissions from these sources, and therefore, no danger of degraded control efficiency from lack of maintenance or equipment failure. The monitoring frequency is justified by the above factors. Should The Department suspect that the applicable emission limit is not being met, however, they may require that a stack test be performed.

6NYCRR 200.6 - Limit On Methylene Chloride Weighed (EU 0-00003: EP 00019/ES 00014)

This monitoring condition has been included to limit the potential for adverse ambient impacts (concentrations) from emissions of methylene chloride. Both source-specific and plant-wide ambient impacts are mitigated via this source-specific limitation. Since the intent is to mitigate annual impacts, the monthly monitoring frequency is justified.

6NYCRR 201-6.5 (d) - Compliance Schedules

This condition serves as a compliance plan to address Order on Consent file no. R5-20050614-507. The

requirement to provide progress reports on a semiannual basis meets the minimum reporting frequency specified in the regulation.

6NYCRR 201-7.2 - VOC Recordkeeping (EU 0-00009)

This monitoring condition specifies the records that must be kept for sources in this emission unit to document compliance with the facility-level cap that has been established on emissions of VOCs. VOC emissions from the unit must be calculated per batch, tallied monthly and added to the facility-wide total. This prevents the annual limit from being exceeded. Vent condenser exit temperatures must be recorded every 15 minutes to demonstrate the degree of control achieved. Finally, the source owner is required to keep a record of the physical characteristics of the VOCs used, since emissions calculations use this data.

6NYCRR 212.4(a) - Recordkeeping for Contaminants Controlled by Scrubber (EU 0-00009)

These conditions were included to provide assurance that emissions of the contaminants specified will not result in adverse ambient impacts (concentrations). Chemical process calculations for those processes involving the use of these contaminants are used to determine the control system parameters needed to hold modeled potential ambient impacts (both annual and short-term) below State guidelines. Process parameters and the physical/chemical characteristics of the contaminant to be scrubbed are used to determine the composition and flow rate of the scrubber liquid needed. This condition requires that records be kept of all of this data and that the scrubber liquid flow rate be monitored and recorded to ensure that the scrubber is operating as required. Since the short-term ambient guideline concentrations are 1 hour average concentrations, the scrubber liquid flow rate monitoring frequency of once every 15 minutes provides for prevention of their exceedence. This frequency will also provide assurance that applicable annual ambient guideline concentrations are not exceeded.

6NYCRR 212.4(a) - Maximum Condenser Exit Temperature Requirement (EU 0-00009)

These conditions were included to provide assurance that emissions of the contaminants specified will not result in adverse ambient impacts (concentrations). Chemical process calculations for those processes involving the use of these contaminants have shown that if the specified outlet temperature is maintained, emissions of these compounds are mitigated to the point that modeled ambient impacts (both annual and short-term) are held below State guidelines. Since the short-term ambient guideline concentrations upon which the limits are in part based are 1 hour average concentrations, the condenser temperature monitoring frequency of once every 15 minutes provides for prevention of their exceedence. This frequency will also provide assurance that applicable annual ambient guideline concentrations are not exceeded.

6NYCRR 200.6 - Maximum Condenser Exit Temperature Requirement (EU 0-00009: EP 00144)

These conditions were included to provide assurance that emissions of the contaminants specified will not result in adverse ambient impacts (concentrations). These conditions also assure control efficiencies claimed for VOC emission calculations are enforceable. Chemical process calculations for those processes involving the use of these contaminants have shown that if the specified outlet temperature is maintained and annual emissions are limited via batch restrictions (in some cases), emissions of these compounds are mitigated to the point that modeled ambient impacts are held below State guidelines. Since the short-term ambient guideline concentrations upon which the limits are in part based are 1 hour average concentrations, the monitoring frequency for condenser temperatures of once every 15 minutes provides for prevention of their exceedence. Annual batch limitations, coupled with the condenser temperature limits, prevent applicable annual ambient guideline concentrations from being exceeded.

6NYCRR 233.3(a)(1) - Maximum Condenser Exit Temperature Requirement for Synthesized Pharmaceutical

Manufacturing Processes (EU 0-00009)

These conditions reduce the emissions of volatile organic compounds (VOC's) from pharmaceutical and cosmetic manufacturing facilities by regulating the temperature at the outlet of condensers. The conditions specify certain temperatures at the outlet from the condensers according to the vapor pressure of the volatile organic compound passing through it. The purpose is to reduce the amount of VOC released to the atmosphere overall to prevent the formation of low-level ozone. The monitoring frequency of once every 15 minutes will allow for early detection and correction of any exceedence of these temperatures, thereby minimizing the time that excess VOCs are emitted. Only certain processes (i.e., non-research and development synthesized pharmaceutical manufacturing processes) are subject to this requirement, since facility VOC emissions are already capped below 50 tons per year, but not below 10 tons per year.

6NYCRR 201-7.2(a) - Limits on Regenerative Thermal Oxidizer Temperatures, Scrubber Liquid Flow and pH (EU 0-00013: ES M0360, M0361, M0362 and M0363)

These conditions were included to provide reasonable compliance assurance that the control efficiency requirements specified in the permit for methylene chloride, methyl alcohol, hydrogen chloride (i.e., HAPs) and VOCs are maintained. The limits on RTO temperature, as well as scrubber liquid flow rate and pH are established during stack testing to be performed under other conditions in this permit. The combustion chamber temperature, and the scrubber liquid flow rate must each be measured and recorded at least once every 15 minutes while controlling contaminant emissions. The scrubber liquid pH must be monitored continuously. These monitoring frequencies allow for prompt action should a problem develop with this control system.

6NYCRR 200.6 - Bypass of Regenerative Thermal Oxidizer (EU 0-00013)

The source owner is required by the USFDA to maintain negative pressure on all manufacturing process rooms. The air flow out of such rooms must, therefore, be sufficient to accomplish this. To maintain adequate air flow for this purpose, but not send a great deal of unnecessary air flow through the control device, the source owner is being allowed to let this room air bypass the new Regenerative Thermal Oxidizer (RTO)/Scrubber control system, but only after all equipment in the room has been shut down and purged of process vapors. This will be monitored via valve position switches. These switches will be controlled by electronic program logic control (PLC) loops such that the bypass valves must be closed prior to restarting and during processing of batches. In addition, backflow prevention line valves, also controlled by PLC loops, will prevent contaminated air in the main manifold from flowing back into the process room and out through the bypass line during bypass periods. This should ensure, to the extent practicable, that process emissions are not misdirected to the bypass vents.