



purpose of these unit-specific conditions.

- b. The affected S30 storage tank farm tanks are subject to 35 IAC 218 Subpart G, Use of Organic Material, which provides that:
  - i. No person shall cause or allow the discharge of more than 3.6 kg/hr (8 lb/hr) of organic material into the atmosphere from any emission unit, except as provided in Condition 1.1.3 (b)(ii) (see also 35 IAC 218.302) and the following exception: If no odor nuisance exists the limitation of 35 IAC 218 Subpart G shall apply only to photochemically reactive material [35 IAC 218.301].
  - ii. Pursuant to 35 IAC 218.302, emissions of organic material in excess of those permitted by Condition 1.1.3(b)(i) (see also 35 IAC 218.301) are allowable if such emissions are controlled by one of the following methods:
    - A. A vapor recovery system which adsorbs and/or condenses at least 85 percent of the total uncontrolled organic material that would otherwise be emitted to the atmosphere [35 IAC 218.302(b)]; or
    - B. Any other air pollution control equipment approved by the Illinois EPA and approved by the USEPA as a SIP revision capable of reducing by 85 percent or more the uncontrolled organic material that would be otherwise emitted to the atmosphere [35 IAC 218.302(c)].
- c. The affected toluene storage tank is subject to the NSPS for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced after July 23, 1984, 40 CFR 60 Subpart Kb, because the affected tank has a capacity greater than or equal to 40 m<sup>3</sup> and is used to store VOLs for which construction, reconstruction, or modification is commenced after July 23, 1984.

1.1.4 Non-Applicability of Regulations of Concern

- a. Except as provided in Special Condition No. 1.1.9(a) (see also 40 CFR 60.116b) storage vessels with design capacity less than 75 m<sup>3</sup> are exempt from the General Provisions of the NSPS and from the provisions of 40 CFR 60 Subpart Kb [40 CFR 60.110b(b)].
- b. The affected toluene storage tank is not subject to the limitations of 35 Ill. Adm. Code 218.120, Control Requirements for Storage Containers of VOL, pursuant to 35 Ill. Adm. Code 218.119, because the materials

stored in the affected tank has a maximum true vapor pressure of less than 0.5 psia and the capacity is less than 151 m<sup>3</sup> (40,000 gal).

- c. The affected toluene storage tank is not subject to the requirements of 35 Ill. Adm. Code 218.121, Storage Containers of VPL, pursuant to 35 Ill. Adm. Code 218.123(a)(2), which exempts stationary storage tanks with a capacity less than 151.42 m<sup>3</sup> (40,000 gal) and pursuant to 35 Ill. Adm. Code 218.123(a)(6), which exempts stationary storage tanks in which volatile petroleum liquid is not stored.
- d. The affected S30 tank farm storage tanks are not subject to the requirements of 35 Ill. Adm. Code 218.122, Loading Operations, because pursuant to 35 Ill. Adm. Code 218.122(c), if no odor nuisance exists the limitations of this 35 Ill. Adm. Code 218.122 shall only apply to the loading of VOL with a vapor pressure of 17.24 kPa (2.5 psia) or greater at 294.3°K (70°F).
- e. The affected S30 tank farm storage tanks are not subject to the control requirements of 35 Ill. Adm. Code 218 Subpart T, because, pursuant to 35 Ill. Adm. Code 218.480(a), the rules of 35 Ill. Adm. Code 218 Subpart T, Pharmaceutical Manufacturing, except for 35 Ill. Adm. Code 218.483 through 218.485, apply to all emission units of VOM, including but not limited to reactors, distillation units, dryers, storage tanks for VOL, equipment for the transfer of VOL, filters, crystallizers, washers, laboratory hoods, pharmaceutical coating operations, mixing operations and centrifuges used in manufacturing, including packaging, of pharmaceuticals, and emitting more than 6.8 kg/day (15 lb/day) and more than 2,268 kg/year (2.5 tons/year) of VOM. If such an emission unit emits less than 2,268 kg/year (2.5 tons/year) of VOM, the requirements of 35 Ill. Adm. Code 218 Subpart T still apply to the emission unit if VOM emissions from the emission unit exceed 45.4 kg/day (100 lb/day).

#### 1.1.5 Operational and Production Limits and Work Practices

- a. Pursuant to 35 Ill. Adm. Code 218.483, the owner or operator of a pharmaceutical manufacturing source shall:
  - i. Provide a vapor balance system that is at least 90 percent effective in reducing VOM emissions from truck or railcar deliveries to storage tanks with capacities equal to or greater than 7.57 m<sup>3</sup> (2,000 gal) that store VOL with vapor pressures greater than 28.0 kPa (4.1 psi) at 294.3°K (70°F) [35 Ill. Adm. Code

218.483(a)]; and

- ii. Install, operate, and maintain pressure/vacuum conservation vents set at 0.2 kPa (0.03 psi) or greater on all storage tanks that store VOL with vapor pressures greater than 10 kPa (1.5 psi) at 294.3°K (70°F) [35 Ill. Adm. Code 218.483(b)].
- b. The owner or operator of a pharmaceutical manufacturing source shall repair any component from which a leak of VOL can be observed. The repair shall be completed as soon as practicable but no later than 15 days after the leak is found. If the leaking component cannot be repaired until the process unit is shut down, the leaking component must then be repaired before the unit is restarted [35 Ill. Adm. Code 218.485].
- c. The Permittee shall follow good operating practices for the conservation vent and carbon adsorption unit S30-CAU-1, including periodic inspection, routine maintenance and prompt repair of defects.
- d. Tank TA-9910 shall only be used for the storage of toluene and/or isopropyl acetate.

1.1.6 Emission Limitations

- a. The affected S30 storage farm tanks are subject to the following:
  - i. This permit is issued based on negligible emissions of volatile organic material (VOM) from the affected toluene storage tank. For this purpose, emissions from all such emission units shall not exceed nominal emission rates of 110 lb/month and 0.33 ton/yr.
  - ii. This permit is issued based on negligible emissions of volatile organic material (VOM) from the affected waste storage tank. For this purpose, emissions from all such emission units shall not exceed nominal emission rates of 110 lb/month and 0.35 ton/yr.
  - iii. The emissions of Hazardous Air Pollutants (HAP) as listed in Section 112(b) of the Clean Air Act from the affected toluene storage tank shall be less than 10 tons/year of any single HAP and 25 tons/year of any combination of such HAPs. As a result of this condition, this permit is issued based on the emissions from Tank TA-9910 not triggering the requirements of Section 112(g) of the Clean Air Act.

- iv. Compliance with annual limits shall be determined on a monthly basis from the sum of the data for the current month plus the preceding 11 months (running 12 month total).
  - v. This permit is issued based upon this project not constituting a major modification in accordance with 35 IAC 203, New Source Review (NSR). Maximum potential emissions from the affected equipment is less than significant net emission increase. (See attachment 1)
- b. The following Plantwide Applicability Limit (PAL) was originally established in the facilities Title V permit, No. 96010011 and has been modified in this condition as demonstrated in Attachment 1 to continue to ensure that the construction and/or modification addressed in the aforementioned permit and corresponding permits for which this PAL originally governed in the facilities Title V permit do not constitute a new major source or major modification pursuant to Title I of the CAA, specifically the federal rules for Prevention of Significant Deterioration (PSD), 40 CFR 52.21 and 35 IAC Part 203 [T1].
- i. Total emissions of volatile organic material (VOM) from the Chemical Manufacturing Area (Buildings A-2, C-2, C-3, C-6, C-7, C-7A, C-7NW, C-10, C-11, C-13, C-14, C-17, C-19, R-7A, R-7B shall not exceed 30.00 tons per year.

1.1.7 Testing Requirements

Upon request of the Illinois EPA an owner or operator of an emission unit which is subject to 35 IAC Part 218 shall, at his own expense, conduct tests in accordance with the applicable test methods and procedures specific in 35 IAC Part 218. Nothing in this Condition (see also 35 IAC 218.105) shall limit the authority of the USEPA pursuant to the Clean Air Act, as amended, to require testing [35 IAC 218.105(i)].

1.1.8 Monitoring Requirements

Pursuant to 35 Ill. Adm. Code 218.105(g), leak detection methods for volatile organic material owners or operators required by 35 Ill. Adm. Code Part 218 to carry out a leak detection monitoring program shall comply with the following requirements:

- a. Leak Detection Monitoring:
  - i. Monitoring shall comply with 40 CFR 60, Appendix A, Method 21 [35 Ill. Adm. Code 218.105(g) (1) (A)];

- ii. The detection instrument shall meet the performance criteria of Method 21 [35 Ill. Adm. Code 218.105(g) (1) (B)];
  - iii. The instrument shall be calibrated before use on each day of its use by the methods specified in Method 21 [35 Ill. Adm. Code 218.105(g) (1) (C)];
  - iv. Calibration gases shall be:
    - A. Zero air (less than 10 ppm of hydrocarbon in air) [35 Ill. Adm. Code 218.105(g) (1) (D) (i)]; and
    - B. A mixture of methane or n-hexane and air at a concentration of approximately, but no less than, 10,000 ppm methane or n-hexane [35 Ill. Adm. Code 218.105(g) (1) (D) (ii)].
  - v. The instrument probe shall be traversed around all potential leak interfaces as close to the interface as possible as described in Method 21 [35 Ill. Adm. Code 218.105(g) (1) (E)].
- b. Pursuant to 35 Ill. Adm. Code 218.105(g) (2), when equipment is tested for compliance with no detectable emissions as required, the test shall comply with the following requirements:
- i. The requirements of Special Condition Nos. 1.1.8(a) (i) through (v) (see also 35 Ill. Adm. Code 218.105(g) (1) (A) through (g) (1) (E)) shall apply [35 Ill. Adm. Code 218.105(g) (2) (A)]; and
  - ii. The background level shall be determined as set forth in Method 21 [35 Ill. Adm. Code 218.105(g) (2) (B)].
- c. Pursuant to 35 Ill. Adm. Code 218.105(g) (3), leak detection tests shall be performed consistent with:
- i. "APTI Course SI 417 controlling Volatile Organic Compound Emissions from Leaking Process Equipment", EPA-450/2-82-015 [35 Ill. Adm. Code 218.105(g) (3) (A)];
  - ii. "Portable Instrument User's Manual for Monitoring VOC Sources", EPA-340/1-86-015 [35 Ill. Adm. Code 218.105(g) (3) (B)];

- iii. "Protocols for Generating Unit-Specific Emission Estimates for Equipment Leaks of VOC and VHAP", EPA-450/3-88-010 [35 Ill. Adm. Code 218.105(g) (3) (C)]; and/or
- iv. "Petroleum Refinery Enforcement Manual", EPA-340/1-80-008 [35 Ill. Adm. Code 218.105(g) (3) (D)].

#### 1.1.9 Recordkeeping Requirements

The Permittee shall maintain records of the following items for each affected S30 storage tank farm tank to demonstrate compliance with Conditions 1.1.3, 1.1.5, and 1.1.6, pursuant to Section 39.5(7) (b) of the Act:

- a. The owner or operator of each storage vessel for which construction, reconstruction, or modification is commenced after July 23, 1984 with a design capacity greater than or equal to 40 m<sup>3</sup>, but less than 75 m<sup>3</sup> shall keep readily accessible records showing the dimension of the storage vessel and an analysis showing the capacity of the storage vessel. Each storage vessel with a design capacity less than 75 m<sup>3</sup> is subject to no other provision of 40 CFR 60 Subpart Kb other than those required by this paragraph. This record shall be kept for the life of the source [40 CFR 60.110b(a), 60.116b(a), and 60.116b(b)].
- b. Records of the leak detecting monitoring pursuant to Special Condition No. 1.1.8, which include the following [Section 39.5(7) (e) of the Act]:
  - i. The date, place and time of sampling or measurements;
  - ii. The date(s) analyses were performed;
  - iii. The company or entity that performed the analyses;
  - iv. The analytical techniques or methods used;
  - v. The results of such analyses; and
  - vi. The operating conditions as existing at the time of sampling or measurement.
- c. Each storage vessel with a design capacity less than 40,000 gallons is subject to no provisions of 35 Ill. Adm. Code Part 218 other than those required by maintaining readily accessible records of the dimensions of the storage vessel and analysis of the capacity of the storage vessel [35 Ill. Adm. Code 218.129(f)].

- d. Pursuant to 35 Ill. Adm. Code 218.489(b), for any leak subject to Special Condition No. 1.1.5(b) (see also 35 Ill. Adm. Code 218.485) which cannot be readily repaired within one hour after detection, the following records shall be kept:
  - i. The name of the leaking equipment [35 Ill. Adm. Code 218.489(b)(1)];
  - ii. The date and time the leak is detected [35 Ill. Adm. Code 218.489(b)(2)];
  - iii. The action taken to repair the leak [35 Ill. Adm. Code 218.489(b)(3)]; and
  - iv. The date and time the leak is repaired [35 Ill. Adm. Code 218.489(b)(4)].
- e. Pursuant to 35 Ill. Adm. Code 218.489(d), for each emission unit used in the manufacture of pharmaceuticals for which the owner or operator of a pharmaceutical manufacturing source claims emission standards are not applicable, because the emissions are below the applicability cutoffs in Special Condition No. 1.1.4(e) (see also 35 Ill. Adm. Code 218.480(a)), the owner or operator shall:
  - i. Maintain a demonstration including detailed engineering calculations of the maximum daily and annual emissions for each such emission unit showing that the emissions are below the applicability cutoffs in Special Condition No. 1.1.4(e) (see also 35 Ill. Adm. Code 218.480(a)) for the current and prior calendar years [35 Ill. Adm. Code 218.489(d)(1)]; and
  - ii. Maintain appropriate operating records for each such emission source to identify whether the applicability cutoffs in Special Condition No. 1.1.4(e) (see also 35 Ill. Adm. Code 218.480(a)) are ever exceeded [35 Ill. Adm. Code 218.489(d)(2)].
- f. Copies of the records shall be made available to the Illinois EPA or the USEPA upon verbal or written request [35 Ill. Adm. Code 218.489(f)].
- g. Records addressing use of good operating practices for the conservation vent:
  - i. Records for periodic inspection of the conservation vent with date, individual performing the inspection, and nature of inspection; and

- ii. Records for prompt repair of defects, with identification and description of defect, effect on emissions, date identified, date repaired, and nature of repair.
- h. Identification of the material stored in the affected S30 tank farm tanks;
- i. The throughput of each affected S30 tank farm tanks, gal/mo and gal/yr; and
- j. The annual VOM and HAP emissions from each affected S30 tank farm tank based on the material stored, the tank throughput, and the applicable emission factors and formulas with supporting calculations.
- k. A demonstration including engineering calculations for the HAP, and VOM control efficiencies of air pollution control equipment, if any, and emissions to the atmosphere for any air pollution control equipment operating in a normal manner. This demonstration shall also show compliance with the control requirements of 35 IAC 218 Subpart T, if applicable to any of the affected chemical manufacturing units;

#### 1.1.10 Reporting Requirements

The Permittee shall promptly notify the Illinois EPA, Compliance Section of noncompliance of an affected S30 tank farm tank with the permit requirements as follows, pursuant to Section 39.5(7)(f)(ii) of the Illinois Environmental Protection Act. Reports shall describe the probable cause of such deviations, and any corrective actions or preventive measures taken:

- a. A person planning to conduct a VOM emissions test to demonstrate compliance with 35 Ill. Adm. Code 218 Subpart T shall notify the Illinois EPA and the USEPA of that intent not less than 30 calendar days before the planned initiation of the test [35 Ill. Adm. Code 218.487(b)].
- b. For each emission unit used in the manufacture of pharmaceuticals for which the owner or operator of a pharmaceutical manufacturing source claims emission standards are not applicable, because the emissions are below the applicability cutoffs in Special Condition No. 1.1.4(e) (see also 35 Ill. Adm. Code 218.480(a)), the owner or operator shall provide written notification to the Illinois EPA and the USEPA within 30 days of a determination that such an emission unit has exceeded the applicability cutoffs in Special Condition No. 1.1.4(e) (see also 35 Ill. Adm. Code 218.480(a)) [35 Ill. Adm. Code 218.489(d)(3)].

- c. The storage of any VOL or VPL other than the material specified in Special Condition No. 1.1.5(d) for the affected toluene storage tank within 30 days of becoming aware of the non-compliance status. This notification shall include a description of the event, the cause for the non-compliance, actions taken to correct the non-compliance, and the steps to be taken to avoid future non-compliance.
- d. Emissions of VOM and/or HAP from the affected S30 tank farm tanks in excess of the limits specified in Special Condition No. 1.1.6 based on the current month's records plus the preceding 11 months within 30 days of such an occurrence.

1.1.11 Operational Flexibility/Anticipated Operating Scenarios

N/A

1.1.12 Compliance Procedures

Compliance with the emission limits shall be based on the recordkeeping requirements in Condition 1.1.9 and the emission factors and formulas listed below:

- a. Determinations of daily and annual emissions for purposes of Condition 1.1.4(a) (see also 35 IAC 218.480) shall be made using both data on the hourly emission rate (or the emissions per unit of throughput) and appropriate daily and annual data from records of emission unit operation (or material throughput or material consumption data). In the absence of representative test data pursuant to Condition 1.1.7(c) (see also 35 IAC 218.487) for the hourly emission rate (or the emissions per unit of throughput) such items shall be calculated using engineering calculations, including the methods described in Appendix B of "Control of Volatile Organic Emissions from Manufacturing of Synthesized Pharmaceutical Products" (EPA-450/2-78-029). This Condition shall not affect the Illinois EPA's or the USEPA's authority to require emission tests to be performed pursuant to Condition 1.1.7(c) (see also 35 IAC 218.487)) [35 IAC 218.480(h)].
- b. For the purpose of estimating VOM emissions from the affected tank, Version 3.1 of the TANKS program is acceptable.

Please note this permit, as it relates to the affected toluene storage tank, supersedes the existing permit, No. 99010045, for said tank.

Also note this permit has been revised to incorporate the affected toluene storage tank along with an increase in emissions for both tanks 2011 and TA-9910 as defined in Attachment 1.

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If you have any questions on this, please call Kevin Smith at 217/782-2113.

Donald E. Sutton, P.E.  
Manager, Permit Section  
Division of Air Pollution Control

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Attachment 1  
NSR Applicability

Table I - Contemporaneous VOM Emission Changes

Project Description	Date Issued	VOM Change (TPY)
MVR Nos. 1 and 2	Aug 97	0.088
Tank TA 2314	Sep 97	0.51
Fermentor Replacements	Nov 97	3.96
Building R-7 Process Center No. 3 Equip.	Nov 97	0.80
S-35 Acetic Acid Loading Station	Nov 97	0.044
Acetic Acid Storage Tank	Dec 97	0.044
R-7A Chromatography Feed Tank	Jan 98	0.10
Fermentor and Seed Tank Replacements	Jan 98	- 1.76
Building C-11 East Reactor	Mar 98	0.22
Building C-10 Equip. Replacement for PC860	May 98	0.22
Utilities Division	Oct 98	1.51
Evap. W/Condenser and Vac. Pump (Cyclo. R-10)	Oct 98	- 0.2836
S-30 Tank Farm Tanks TA-9602 and TA-9705	Oct 98	0.044
R-9 PC952 Centrifuge Dryer and Cogeim Dryer	Dec 98	0.50
C2 Tank replacement and C-7A Vacuum System	Dec 98	0.022
Rental Evap (Cyclosporine R-10)	Feb 99	0.018
R-10 Pilot Plant Exp. Equip. and Thermal Ox.	Mar 99	0.66
S-34 Tank Farm (Replacement Tank T-1987)	Jul 99	0.26
BLDG. R12 Unit Operations Lab	Nov 99	0.10
S30 Tank farm Tank No. 2011	Mar 00	0.1950
M8 Gasoline Tank	Apr 00	0.250
BLDG. R12 Lab No. 3 Fume Hood	Apr 00	0.10
M3B PARD Tablet Coater No.2	May 00	0.220
SPD Chem Pilot Plant BLDG R8, Rm. 150	Dec 00	0.660
Emergency Boiler No. T4	Jan 01	1.50
PPD M2 Line 7 Liquid Products Fill Room	Jan 01	0.063
SPD R2B Process Tanks (4)	Feb 01	0.20
SPD R3 50 GAL. Collection Tank	Feb 01	0.220
PPD M3 Weigh Booth #4	Mar 01	0.50
SPD C10, PC-860 Reactor Replacement	Mar 01	0.25
SPD R7 PC-1 and 2 Reactors VOM Increase	Mar 01	1.56
SPD Chem Area Portable Reactor RX-1616	Apr 01	0.37
SPD R9 PC-951 VOM Increase	Apr 01	0.20
SPD R9 Dryer DR-920 Replacement	Apr 01	0.24
SPD C10 Tumble Dryer DR-0868 and Vac. System	Apr 01	0.40
SPD S-7 Tank farm Portable container Filling	Jul 01	0.050
SPD C10 Drum Washer	Aug 01	0.1
SPD Shem MFG. Portable Equipment	Oct 01	0.2
SPD C10 PC-803 Reactor and Process Condenser	Oct 01	0.3
R3 Tank 58 and R3 Tank 92	Oct 01	0.07
R2B Tank 106 and R2B Tank 51	Oct 01	0.07
R5/R6 Cleaning Solution Tank	Oct 01	0.01
Cold Solvent Cleaning Units (3)	Oct 01	0.025
Boiler T5	Jan 02	1.2
SPD BLDG R7A Process Equipment	Jan 02	0.75
GPRD Pilot Plant SovPurifProc (12 Units)	Feb 02	0.105
Building C-10, PC-860 Feed Tank	Mar 02	0.08
PPD/GPRD J2 Pharmaceutical Fill/Finish Fac.	Mar 02	0.1
S-27 Tank Farm Modification	Apr 02	2.2
Building C-10, PC-830 Reactor Replacement	Apr 02	0.375
Building C-10, PC-806 Reactor Replacement	Apr 02	- 1.487
Building R10 Amicon Column (Amicon OR-2)	Jun 02	0.052
<b>Total</b>		18.1819

Table II

Past Two Year Actual VOM Emissions From the Chemical Manufacturing Area

Period of Emissions	Total Actual VOM Emissions (Tons)
1/1/2000-12/31/2000	38.28
1/1/2001-12/31/2001	31.80
Total	70.08
Annual Average	35.04

Table III

Proposed Plantwide Applicability Limit (PAL) For The Chemical Manufacturing Area

Description	VOM Emissions Tons per Year
Existing Title V Permit PAL VOM Limit for Chemical Manufacturing Area	43.82
Years 200-2001 Average Total Emissions	35.04
Proposed VOM Emissions Plantwide Applicability Limit (PAL); Replaces Existing Title V Permit PAL VOM Limit for Chemical Manufacturing Area	30.00
Net Contemporaneous Change in Emissions	- 5.04

Table IV

Net VOM Emission Increase

Description	VOM Emissions (tons/yr)
Total From Table I	18.1819
Tank 2011 Contemporaneous Increase	0.155
Tank 9910 Contemporaneous Increase	0.110
Total From Table III	- 5.040
Net Change	13.4069

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