

ILLINOIS POLLUTION CONTROL BOARD
August 21, 2008

IN THE MATTER OF:)
)
ABBOTT LABORATORIES' PROPOSED) R08-8
SITE SPECIFIC AMENDMENT TO) (Rulemaking - Air)
APPLICABILITY SECTION OF ORGANIC)
MATERIAL EMISSION STANDARDS AND)
LIMITATIONS FOR THE CHICAGO AREA;)
SUBPART T: PHARMACEUTICAL)
MANUFACTURING (35 ILL. ADM. CODE)
218.480(b)))

Adopted Rule. Final Order.

OPINION AND ORDER OF THE BOARD (by N.J. Melas):

On September 4, 2007, Abbott Laboratories (Abbott) filed a proposal for site-specific rulemaking pursuant to Section 28 of the Environmental Protection Act (Act) (415 ILCS 5/28 (2006), to allow it “additional operational flexibility” with regard to emissions from certain tunnel dryers and fluid bed dryers at its pharmaceutical manufacturing facility located in Libertyville Township, Lake County. At Abbott’s request, on October 4, 2008, the Board ordered immediate publication of the rules for first notice under the Illinois Administrative Procedure Act (APA), 5 ILCS 100/1-1 *et seq* (2006). *See*, respectively, 35 Ill. Adm. Code Sections 102.202(g) and 101.512.

The proposal was published at 31 *Ill. Reg.* 14581 (Oct. 26, 2007). The Board held a hearing on the proposal in Libertyville, Lake County on March 7, 2008. The sole participants were Abbott and the Illinois Environmental Protection Agency (IEPA); IEPA filed a post-hearing comment in support of the requested relief.

On June 19, 2008, the Board adopted a second-notice proposal for submission to the Joint Committee on Administrative Rules (JCAR) under the APA. The proposal incorporated changes requested by Abbott and discussed at hearing. JCAR voted a certificate of no objection at its August 19, 2008 meeting. As JCAR suggested no changes, the final rule the Board adopts is identical to the rule as proposed at second notice.

By today’s action, the Board adopts a final rule, to become effective upon its filing by the Clerk with the Secretary of State. This opinion will set out the proposal’s background, summarize the proposal, and discuss the evidence presented and public comments made concerning the economic reasonableness and technical feasibility of the rule.

BACKGROUND

Abbott owns a pharmaceutical manufacturing facility located in Libertyville Township, Lake County, Illinois (the Facility). Abbott’s operations are subject to the emissions standards for volatile

organic materials (VOM) at 35 Ill. Adm. Code, Subpart T – Pharmaceutical Manufacturing (Subpart T rules). As currently written, Section 218.480(b) contains certain exemptions that are only applicable to Abbott’s air suspension coater/dryer, fluid bed dryers, tunnel dryers, and Accelacotas located at the Facility.

Abbott proposed to amend these site-specific exemptions by “capping” and lowering the overall emissions allowable under the exemptions from its tunnel dryers numbered #1, #2, #3 and #4, and fluid bed dryers numbered #1, #2 and #3, and calculating the amount of exempted emissions from the dryers based on the actual combined emissions from the dryers. Abbott believes that, if adopted, the proposed amendment would reduce the overall allowable emissions from these units while increasing Abbott’s operational flexibility, by allowing it to make preferential use of the more efficient fluid bed dryers.

Abbott’s proposal to amend 35 Ill. Adm. Code 218.480(b), as modified by Abbott’s February 29, 2008 filing, is as follows (proposed amendments are shown by underlining new language and striking through deleted language:

- b) Notwithstanding subsection (a) of this Section, the air suspension coater/dryer, fluid bed dryers, tunnel dryers, and Accelacotas located in Libertyville Township, Lake County, Illinois shall be exempt from the rules of this Subpart, except for Sections 218.483 through 218.485, if emissions of VOM not vented to air pollution control equipment do not exceed the following levels:
- 1) For the air suspension coater/dryer: 2,268 kg/year (2.5 tons/year);
 - 2) Except as set forth in subsection 218.480(b)(4) of this Section, for ~~For~~ each fluid bed dryer: 4,535 kg/year (5.0 tons/year);
 - 3) Except as set forth in subsection 218.480(b)(4) of this Section, for ~~For~~ each tunnel dryer: 6,803 kg/year (7.5 tons/year); ~~and~~
 - 4) For fluid bed dryers #1, #2, and #3 and for tunnel dryers #1, #2, #3, and #4, the combined total annual emissions from the dryers listed in this subsection 218.480(b)(4) shall not exceed 18,688 kg/year (20.6 tons/year). [BOARD NOTE: tunnel dryers are otherwise referred to as warm air dryers]; and
 - 45) For each Accelacota: 6,803 kg/year (7.5 tons/year).

PROCEDURAL HISTORY

As previously stated, Abbott filed this proposal on September 4, 2007. As well as the text of the proposed amendment to 35 Ill. Adm. Code 218.480(b), Abbott's original filing included a Statement of Reasons (S.R.) and three exhibits (Exh.): an Aerial Photograph of Abbott Park and Vicinity, Libertyville Township, Illinois (Exh. 1), a document entitled *Improving Air Quality with Economic Incentive Programs* [EIP], Doc. No.EPA-452/R01-001, United States Environmental Protection Agency (USEPA), Office of Air and

Radiation, Office of Air Quality Planning and Standards (Jan. 2001) (Exh. 2), and a table entitled "Historical VOM Air Emissions from Tunnel Dryers and Fluid Bed Dryers at the Abbott Park Facility." (Exh. 3). The proposal was accompanied by motions to waive the 200-signature requirement, and a request for expedited decision.

On October 4, 2008, the Board waived the 200 signatures, accepted the proposal for hearing, and ordered publication of the rules for first notice without comment on the merits. However, the Board denied Abbott's motion for expedited decision, citing resource and time constraints. By letter of October 18, 2008, the Board requested the Director of the Department of Commerce and Economic Opportunity (DCEO) to request an economic impact study concerning this rulemaking as required by Section 27 (b) of the Act. 415 ILCS 5/27(b) (2006). To date, DCEO has not responded to the request.

The proposal was published at 31 Ill. Reg.14581 (Oct. 26, 2007). JCAR filed its technical comment on the first notice on October 18, 2007, and its Request for Economic and Budgetary Effects on October 22, 2008.

Pursuant to a January 31, 2008 hearing officer order setting a March 7, 2008 hearing date, and asking questions to be addressed at hearing, Abbott pre-filed testimony of two of its employees: Diane Beno and Robert C. Wells. On February 29, 2008, Abbott filed a motion to modify its original proposal to better take into account data on its historical VOM emissions. The March 4, 2008 hearing officer order granted the motion to modify, but reserved ruling on a motion to revise Exhibit 3, the table of historical VOM emissions to be presented at hearing. The order additionally specified questions the Board requested the participants to address at hearing.

The Board held a hearing on the proposal in Libertyville, Lake County on March 7, 2008 to receive testimony and comment concerning the merits and the economic impact of the proposed rule (including the absence of any DCEO study).¹ The sole participants were counsel for, and employees of, Abbott and IEPA; no members of the public attended the hearing.

Abbott presented the testimony of two witnesses in support of its proposal: Diane Beno, the plant manager at the Facility's Building AP16, and Robert C. Wells Air Manager for Environmental Support in Abbott's Global Environmental Health & Safety Department. The three previously identified exhibits were entered at hearing, and the hearing officer granted the requested leave to file a revised exhibit *i.e.*, the aerial photograph of the Abbott Facility (Exh. 1), USEPA EIP document (Exh. 2), and a revised table of historical VOM emissions (Exh. 3). Three additional exhibits were entered: a chart entitled "Granulation Process—Fluid Bed Drying" and "Granulation Process—Tunnel Drying" (Exh. 4), Ms. Well's pre-filed testimony (Exh. 5), and the questions contained in the March 4, 2008 hearing officer order (Exh. 6).

The IEPA presented one witness, solely to answer questions posed by the Board: Yoginder Mahajan, an Engineer with the Air Quality Planning Section of the IEPA Bureau of Air. During the course of hearing, Abbott and the IEPA advised that USEPA had requested Abbott to provide IEPA with

¹ On April 7, 2008, Abbott filed an unopposed motion to correct the transcript, which is granted. Citations to the transcript (Tr.) in this opinion are to the transcript as corrected consistent with the motion granted today.

additional data. The hearing officer accordingly set May 1, 2008 as the filing date for the participants' closing comments to the Board, to facilitate preparation and consideration of USEPS data requests. On May 1, 2008, the Board received timely post hearing comments from Abbott (PC 1) and IEPA (PC 2). In its comment, IEPA stated that:

Abbott proposed a source-specific cap on emissions of volatile organic material ("VOM") from its combined fluid bed dryers and tunnel dryers in lieu of rate-based limits provided in Section 218.480(b). The net effect of the proposal will result in a reduction of 24.5 tons per year of VOM emissions.

The Illinois EPA has determined that the proposal will not adversely affect the air quality in Illinois. The Illinois EPA further consulted the United States Environmental Protection Agency ("USEPA") and concluded that the proposal is consistent with the guidelines of USEPA's Economic Incentive Program. Accordingly, after reviewing Abbott's petition, the Illinois EPA supports the requested site-specific relief. PC 2 at 1.

On June 19, 2008, the Board adopted a second-notice proposal for submission to JCAR under the APA. The proposal incorporated changes requested by Abbott and discussed at hearing. JCAR voted a certificate of no objection at its August 19, 2008 meeting.

UNCONTESTED EVIDENCE CONCERNING ABBOTT'S PROCESS AND EMISSIONS

Abbott's Process

In Building AP16 at the Facility, Abbott produces intermediate and final pharmaceutical product formulation using batch production processes. Active and inactive ingredients are combined with a liquid in a process called "massing to form uniform granules. Wet granules are dried in tunnel dryers or fluid bed dryers and then further processed into tablets or capsules. Beno at 2. The massing fluid, which is typically either water or ethanol, is evaporated from the solid material in the drying step. *Id.* If an organic solvent is volatilized from the dryer, it is emitted to the ambient air as VOM. The quantity of VOM emissions varies for different products, and is calculated from the quantity of VOM added to the mixture and loss factors defined for the dryers and specified in the Clean Air Act Permit Program (CAAPP) Permit for the Facility. *Id.*

Abbott's proposed site-specific amendment covers four tunnel dryers and three fluid bed dryers. Beno at 3. The technologies are not interchangeable, although individual dryers of the same type can be used in combination or interchangeably. In the use of tunnel dryers, materials to be dried are spread on trays and placed in a warming chamber or "tunnel" that circulates warm air over and under the trays. *Id.*

A fluid bed dryer is a large vertical cylindrical shaped vessel with a diffuser that blows warm air up from the bottom of the vessel. Beno at 3. The wet intermediate granules are loaded into the dryer and flow upward, suspended in the warm air stream. Abbott has increased its use of fluid bed dryers for recently developed products because they are more efficient and produce a more uniform product than the tunnel dryers. Abbott anticipates increased use of water for the massing fluid in future products. Abbott expects that this preferential use of fluid bed dryers and water-based products will continue. *Id.*

“Process trains” are designed to accommodate the manufacture of batches in large or small scales. Beno at 4. The scale of a given batch plays an important role in determining which of the dryers will be most efficient. Also, given the amount of cleaning (up to three days) required between batches of different products, Abbott prefers to continue running batches of the same product consecutively in the process train to minimize this cleaning and lost production time. *Id.*

Abbott explains that, for practical purposes, Section 218.480(b) defines a 12-month total VOM limit on each individual dryer. Beno at 4. To ensure compliance with each dryer’s limit, for a particular batch Abbott may need to utilize a dryer with low VOM emissions during the last 12 months, instead of using the most efficient dryer from a production scale viewpoint. This can result in inefficient use of a large-scale process train to dry a small batch of product to maintain the equipment-specific VOM limits. Beno at 4-5.

Total annual emissions from a dryer result from the quantity of organic solvent removed from the different products processed in a dryer over a rolling 12-month period. The assignment of a “campaign” of products to dryers involves operating factors. But, the VOM emission threshold acts as an overriding factor. Beno at 5. This increases the operational cost, but results in no environmental benefit, because the actual emissions will be the same as if the campaign would have used the original equipment. *Id.*

Abbott’s Emissions

Subpart T requires VOM controls for tunnel dryers and fluid bed dryers if the actual emissions exceed 7.5 tons per year (tpy) for a tunnel dryer or 5 tpy for a fluid bed dryer. Tr. at 25. If uncontrolled, the four tunnel dryers and three fluid bed dryers involved here have a potential to emit 45 tpy. The seven dryers’ actual emissions vary; in recent years, tunnel dryer emissions have varied from 0.6 tpy to 5.6 tpy, while those of fluid bed dryers have ranged from 0.1 tpy to 3.9 tpy per year of operation. Tr. at 25-26.

At hearing, in response to a Board queries, Abbott verified that the economics presented in the R96-10 rulemaking had not changed. Tr. at 31-32. Similarly, since then there have been no fundamental changes in emission control technology. Abbott’s lower emissions since 2000 have been the result of variations in demand in the pharmaceutical industry, as well as Abbott’s use of water-based solvents where available. Tr. at 33. Abbott does not expect emissions to increase over time. Tr. at 35. The only organic solvent Abbott has used during the last 10 years is ethanol. Since 2002, Abbott has been using beverage grade ethanol (which does not contain methanol as the denaturant.) While it is impractical to change ethanol-based processes to water-based processes because of United States Food and Drug Administration (FDA) concerns, Abbott does expect to see an increased use of water in new products. Tr. at 40. While fluid bed dryers are, by their mode of operation, more efficient than tunnel dryers, Abbott does not expect to be able to phase out tunnel dryers entirely, as switching the technologies can have an impact on the drug product so as to raise FDA concerns.

USEPA Economic Incentive Program

As a result of discussions between Abbott, IEPA, and USEPA, a compliance alternative was developed called a Source Specific Emissions Cap (SSEC) under USEPA’s EIP. *See* USEPA EIP document (Exh. 2). The general principles of the EIP are integrity, equity, and environmental benefit.

Tr. at 28-30. The SSEC would allow Abbott to combine its future emissions limits for all seven dryers, and establish a limit below the historical actual emissions, rather than the previously allowable emissions or emissions allowable without control. Tr. at 27.

Based on the highest two-year emission period (1999-2000) during the preceding ten-year period, Abbott calculated baseline emissions of 22.9 tpy². Reducing that by 10% to guarantee a net environmental benefit, the new emission limit would be 20.6 tpy for the seven dryers. This is less than half the current 45 tpy effective limit for the dryers. Tr. at 27-28.

At hearing, the Agency answered questions from the Board concerning USEPA's EIP. The Agency's Mr. Mahajan clarified that the Board could properly consider Abbott's request even though the state has not formally adopted an EIP policy, and has no current plans to do so. Tr. at 49. He also confirmed that IEPA and USEPA consider Abbott's proposal as satisfying EIP principles. Mr. Mahajan confirmed that the SSEC elements are those described in the USEPS guidance, and that the proposed combined VOM limit was consistent with EIP guidelines. Tr. at 49-54.

Economic and Budgetary Information

At hearing, Abbott was reminded that JCAR had requested an Economic and Budgetary Effects analysis be submitted to it with any second notice rule. Abbott presented testimony that the proposed rule applies only to its units. The proposed rule will allow for increased operational flexibility at Abbott's facility, which, in turn will result in more efficient and cost effective production of pharmaceutical products. Moreover, the proposal will not impose any new requirements on Abbott or the Agency. Tr. at 9-10.

BOARD CONCLUSION

Based on the undisputed facts in this record, the Board finds that adoption of Abbott's proposed rule will result in definite, if unquantifiable, economic savings to Abbott by allowing it to use its business judgment in determining the most efficient use of its process equipment. At the same time, adoption of the alternative compliance method suggested will result in net reductions of VOM emissions from Abbott's facility. The Board accordingly finds that the adopted rule is economically reasonable, technically feasible, and will not impose a negative economic impact on the State of Illinois within the meaning of Section 27(b) of the Act. 415 ILCS 5/27(b) (2006).

ORDER

The Board directs the Clerk to file the following adopted rules with the Secretary of State, to become effective upon filing (amendments adopted in this rulemaking continue to be indicated in the order, but will not be so indicated in final filed rule text):

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE B: AIR POLLUTION
CHAPTER I: POLLUTION CONTROL BOARD

² Use of this method of emissions calculations was recommended by IEPA and USEPA. Tr. at 44-46.

SUBCHAPTER c: EMISSIONS STANDARDS AND
LIMITATIONS FOR STATIONARY SOURCES

PART 218
ORGANIC MATERIAL EMISSION STANDARDS AND
LIMITATIONS FOR THE CHICAGO AREA

SUBPART A: GENERAL PROVISIONS

Section	
218.100	Introduction
218.101	Savings Clause
218.102	Abbreviations and Conversion Factors
218.103	Applicability
218.104	Definitions
218.105	Test Methods and Procedures
218.106	Compliance Dates
218.107	Operation of Afterburners
218.108	Exemptions, Variations, and Alternative Means of Control or Compliance Determinations
218.109	Vapor Pressure of Volatile Organic Liquids
218.110	Vapor Pressure of Organic Material or Solvent
218.111	Vapor Pressure of Volatile Organic Material
218.112	Incorporations by Reference
218.113	Monitoring for Negligibly-Reactive Compounds
218.114	Compliance with Permit Conditions

SUBPART B: ORGANIC EMISSIONS FROM STORAGE AND LOADING OPERATIONS

Section	
218.119	Applicability for VOL
218.120	Control Requirements for Storage Containers of VOL
218.121	Storage Containers of VPL
218.122	Loading Operations
218.123	Petroleum Liquid Storage Tanks
218.124	External Floating Roofs
218.125	Compliance Dates
218.126	Compliance Plan (Repealed)
218.127	Testing VOL Operations
218.128	Monitoring VOL Operations
218.129	Recordkeeping and Reporting for VOL Operations

SUBPART C: ORGANIC EMISSIONS FROM MISCELLANEOUS EQUIPMENT

Section	
218.141	Separation Operations
218.142	Pumps and Compressors
218.143	Vapor Blowdown
218.144	Safety Relief Valves

SUBPART E: SOLVENT CLEANING

Section	
218.181	Solvent Cleaning in General
218.182	Cold Cleaning
218.183	Open Top Vapor Degreasing
218.184	Conveyorized Degreasing
218.185	Compliance Schedule (Repealed)
218.186	Test Methods

SUBPART F: COATING OPERATIONS

Section	
218.204	Emission Limitations
218.205	Daily-Weighted Average Limitations
218.206	Solids Basis Calculation
218.207	Alternative Emission Limitations
218.208	Exemptions from Emission Limitations
218.209	Exemption from General Rule on Use of Organic Material
218.210	Compliance Schedule
218.211	Recordkeeping and Reporting
218.212	Cross-Line Averaging to Establish Compliance for Coating Lines
218.213	Recordkeeping and Reporting for Cross-Line Averaging Participating Coating Lines
218.214	Changing Compliance Methods
218.215	Wood Furniture Coating Averaging Approach
218.216	Wood Furniture Coating Add-On Control Use
218.217	Wood Furniture Coating Work Practice Standards

SUBPART G: USE OF ORGANIC MATERIAL

Section	
218.301	Use of Organic Material
218.302	Alternative Standard
218.303	Fuel Combustion Emission Units
218.304	Operations with Compliance Program

SUBPART H: PRINTING AND PUBLISHING

Section	
218.401	Flexographic and Rotogravure Printing
218.402	Applicability
218.403	Compliance Schedule
218.404	Recordkeeping and Reporting
218.405	Lithographic Printing: Applicability
218.406	Provisions Applying to Heatset Web Offset Lithographic Printing Prior to March 15, 1996
218.407	Emission Limitations and Control Requirements for Lithographic Printing Lines On and After March 15, 1996
218.408	Compliance Schedule for Lithographic Printing On and After March 15, 1996

218.409	Testing for Lithographic Printing On and After March 15, 1996
218.410	Monitoring Requirements for Lithographic Printing
218.411	Recordkeeping and Reporting for Lithographic Printing

SUBPART Q: SYNTHETIC ORGANIC CHEMICAL AND POLYMER MANUFACTURING PLANT

Section	
218.421	General Requirements
218.422	Inspection Program Plan for Leaks
218.423	Inspection Program for Leaks
218.424	Repairing Leaks
218.425	Recordkeeping for Leaks
218.426	Report for Leaks
218.427	Alternative Program for Leaks
218.428	Open-Ended Valves
218.429	Standards for Control Devices
218.430	Compliance Date (Repealed)
218.431	Applicability
218.432	Control Requirements
218.433	Performance and Testing Requirements
218.434	Monitoring Requirements
218.435	Recordkeeping and Reporting Requirements
218.436	Compliance Date

SUBPART R: PETROLEUM REFINING AND RELATED INDUSTRIES; ASPHALT MATERIALS

Section	
218.441	Petroleum Refinery Waste Gas Disposal
218.442	Vacuum Producing Systems
218.443	Wastewater (Oil/Water) Separator
218.444	Process Unit Turnarounds
218.445	Leaks: General Requirements
218.446	Monitoring Program Plan for Leaks
218.447	Monitoring Program for Leaks
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218.449	Reporting for Leaks
218.450	Alternative Program for Leaks
218.451	Sealing Device Requirements
218.452	Compliance Schedule for Leaks
218.453	Compliance Dates (Repealed)

SUBPART S: RUBBER AND MISCELLANEOUS PLASTIC PRODUCTS

Section	
218.461	Manufacture of Pneumatic Rubber Tires
218.462	Green Tire Spraying Operations
218.463	Alternative Emission Reduction Systems

218.464	Emission Testing
218.465	Compliance Dates (Repealed)
218.466	Compliance Plan (Repealed)

SUBPART T: PHARMACEUTICAL MANUFACTURING

Section	
218.480	Applicability
218.481	Control of Reactors, Distillation Units, Crystallizers, Centrifuges and Vacuum Dryers
218.482	Control of Air Dryers, Production Equipment Exhaust Systems and Filters
218.483	Material Storage and Transfer
218.484	In-Process Tanks
218.485	Leaks
218.486	Other Emission Units
218.487	Testing
218.488	Monitoring for Air Pollution Control Equipment
218.489	Recordkeeping for Air Pollution Control Equipment

SUBPART V: BATCH OPERATIONS AND AIR OXIDATION PROCESSES

Section	
218.500	Applicability for Batch Operations
218.501	Control Requirements for Batch Operations
218.502	Determination of Uncontrolled Total Annual Mass Emissions and Average Flow Rate Values for Batch Operations
218.503	Performance and Testing Requirements for Batch Operations
218.504	Monitoring Requirements for Batch Operations
218.505	Reporting and Recordkeeping for Batch Operations
218.506	Compliance Date
218.520	Emission Limitations for Air Oxidation Processes
218.521	Definitions (Repealed)
218.522	Savings Clause
218.523	Compliance
218.524	Determination of Applicability
218.525	Emission Limitations for Air Oxidation Processes
218.526	Testing and Monitoring
218.527	Compliance Date (Repealed)

SUBPART W: AGRICULTURE

Section	
218.541	Pesticide Exception

SUBPART X: CONSTRUCTION

Section	
218.561	Architectural Coatings
218.562	Paving Operations
218.563	Cutback Asphalt

SUBPART Y: GASOLINE DISTRIBUTION

Section	
218.581	Bulk Gasoline Plants
218.582	Bulk Gasoline Terminals
218.583	Gasoline Dispensing Operations - Storage Tank Filling Operations
218.584	Gasoline Delivery Vessels
218.585	Gasoline Volatility Standards
218.586	Gasoline Dispensing Operations - Motor Vehicle Fueling Operations

SUBPART Z: DRY CLEANERS

Section	
218.601	Perchloroethylene Dry Cleaners (Repealed)
218.602	Applicability (Repealed)
218.603	Leaks (Repealed)
218.604	Compliance Dates (Repealed)
218.605	Compliance Plan (Repealed)
218.606	Exception to Compliance Plan (Repealed)
218.607	Standards for Petroleum Solvent Dry Cleaners
218.608	Operating Practices for Petroleum Solvent Dry Cleaners
218.609	Program for Inspection and Repair of Leaks
218.610	Testing and Monitoring
218.611	Applicability for Petroleum Solvent Dry Cleaners
218.612	Compliance Dates (Repealed)
218.613	Compliance Plan (Repealed)

SUBPART AA: PAINT AND INK MANUFACTURING

Section	
218.620	Applicability
218.621	Exemption for Waterbase Material and Heatset Offset Ink
218.623	Permit Conditions (Repealed)
218.624	Open Top Mills, Tanks, Vats or Vessels
218.625	Grinding Mills
218.626	Storage Tanks
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218.630	Clean Up
218.636	Compliance Schedule
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SUBPART BB: POLYSTYRENE PLANTS

Section	
218.640	Applicability
218.642	Emissions Limitation at Polystyrene Plants
218.644	Emissions Testing

SUBPART CC: POLYESTER RESIN PRODUCT MANUFACTURING PROCESS

Section

218.660	Applicability
218.666	Control Requirements
218.667	Compliance Schedule
218.668	Testing
218.670	Recordkeeping and Reporting for Exempt Emission Units
218.672	Recordkeeping and Reporting for Subject Emission Units

SUBPART DD: AEROSOL CAN FILLING

Section	
218.680	Applicability
218.686	Control Requirements
218.688	Testing
218.690	Recordkeeping and Reporting for Exempt Emission Units
218.692	Recordkeeping and Reporting for Subject Emission Units

SUBPART FF: BAKERY OVENS (REPEALED)

Section	
218.720	Applicability (Repealed)
218.722	Control Requirements (Repealed)
218.726	Testing (Repealed)
218.727	Monitoring (Repealed)
218.728	Recordkeeping and Reporting (Repealed)
218.729	Compliance Date (Repealed)
218.730	Certification (Repealed)

SUBPART GG: MARINE TERMINALS

Section	
218.760	Applicability
218.762	Control Requirements
218.764	Compliance Certification
218.766	Leaks
218.768	Testing and Monitoring
218.770	Recordkeeping and Reporting

SUBPART HH: MOTOR VEHICLE REFINISHING

Section	
218.780	Emission Limitations
218.782	Alternative Control Requirements
218.784	Equipment Specifications
218.786	Surface Preparation Materials
218.787	Work Practices
218.788	Testing
218.789	Monitoring and Recordkeeping for Control Devices
218.790	General Recordkeeping and Reporting (Repealed)
218.791	Compliance Date
218.792	Registration

218.875	Applicability of Subpart BB (Renumbered)
218.877	Emissions Limitation at Polystyrene Plants (Renumbered)
218.879	Compliance Date (Repealed)
218.881	Compliance Plan (Repealed)
218.883	Special Requirements for Compliance Plan (Repealed)
218.886	Emissions Testing (Renumbered)

SUBPART PP: MISCELLANEOUS FABRICATED PRODUCT MANUFACTURING PROCESSES

Section	
218.920	Applicability
218.923	Permit Conditions (Repealed)
218.926	Control Requirements
218.927	Compliance Schedule
218.928	Testing
218.929	Cementable and Dress or Performance Shoe Leather

SUBPART QQ: MISCELLANEOUS FORMULATION MANUFACTURING PROCESSES

Section	
218.940	Applicability
218.943	Permit Conditions (Repealed)
218.946	Control Requirements
218.947	Compliance Schedule
218.948	Testing

SUBPART RR: MISCELLANEOUS ORGANIC CHEMICAL MANUFACTURING PROCESSES

Section	
218.960	Applicability
218.963	Permit Conditions (Repealed)
218.966	Control Requirements
218.967	Compliance Schedule
218.968	Testing

SUBPART TT: OTHER EMISSION UNITS

Section	
218.980	Applicability
218.983	Permit Conditions (Repealed)
218.986	Control Requirements
218.987	Compliance Schedule
218.988	Testing

SUBPART UU: RECORDKEEPING AND REPORTING

Section	
218.990	Exempt Emission Units
218.991	Subject Emission Units

218.APPENDIX A:	List of Chemicals Defining Synthetic Organic Chemical and Polymer Manufacturing
218.APPENDIX B:	VOM Measurement Techniques for Capture Efficiency (Repealed)
218.APPENDIX C:	Reference Methods and Procedures
218.APPENDIX D:	Coefficients for the Total Resource Effectiveness Index (TRE) Equation
218.APPENDIX E:	List of Affected Marine Terminals
218.APPENDIX G:	TRE Index Measurements for SOCOMI Reactors and Distillation Units
218.APPENDIX H:	Baseline VOM Content Limitations for Subpart F, Section 218.212 Cross-Line Averaging

AUTHORITY: Implementing Section 10 and authorized by Sections 27, 28, 28.5 of the Environmental Protection Act [415 ILCS 5/10 and 28.5].

SOURCE: Adopted at R91-7 at 15 Ill. Reg. 12231, effective August 16, 1991; amended in R91-24 at 16 Ill. Reg. 13564, effective August 24, 1992; amended in R91-28 and R91-30 at 16 Ill. Reg. 13864, effective August 24, 1992; amended in R93-9 at 17 Ill. Reg. 16636, effective September 27, 1993; amended in R93-14 at 18 Ill. Reg. at 1945, effective January 24, 1994; amended in R94-12 at 18 Ill. Reg. 14973, effective September 21, 1994; amended in R94-15 at 18 Ill. Reg. 16392, effective October 25, 1994; amended in R94-16 at 18 Ill. Reg. 16950, effective November 15, 1994; amended in R94-21, R94-31 and R94-32 at 19 Ill. Reg. 6848, effective May 9, 1995; amended in R94-33 at 19 Ill. Reg. 7359, effective May 22, 1995; amended in R96-13 at 20 Ill. Reg. 14428, effective October 17, 1996; amended in R97-24 at 21 Ill. Reg. 7708, effective June 9, 1997; amended in R97-31 at 22 Ill. Reg. 3556, effective February 2, 1998; amended in R98-16 at 22 Ill. Reg. 14282, effective July 16, 1998; amended in R02-20 at 27 Ill. Reg. 7283, effective April 8, 2003; amended in R04-12/20 at 30 Ill. Reg. 9684, effective May 15, 2006; amended in R06-21 at 31 Ill. Reg. 7086, effective April 30, 2007; amended in R08-8 at 32 Ill. Reg. _____, effective _____.

SUBPART T: PHARMACEUTICAL MANUFACTURING

Section 218.480 Applicability

- a) The rules of this Subpart, except for Sections 218.483 through 218.485 of this Part, 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 lbs/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 this Subpart still apply to the emission unit if VOM emissions from the emission unit exceed 45.4 kg/day (100 lbs/day).
- b) Notwithstanding subsection (a) of this Section, the air suspension coater/dryer, fluid bed dryers, tunnel dryers, and Accelacotas located in Libertyville Township, Lake County, Illinois shall be exempt from the rules of this Subpart, except for Sections 218.483

through 218.485, if emissions of VOM not vented to air pollution control equipment do not exceed the following levels:

- 1) For the air suspension coater/dryer: 2,268 kg/year (2.5 tons/year);
 - 2) Except as set forth in subsection 218.480(b)(4) of this Section, for ~~For~~ each fluid bed dryer: 4,535 kg/year (5.0 tons/year);
 - 3) Except as set forth in subsection 218.480(b)(4) of this Section, for ~~For~~ each tunnel dryer: 6,803 kg/year (7.5 tons/year); and
 - 4) For fluid bed dryers #1, #2, and #3 and for tunnel dryers #1, #2, #3, and #4, the combined total annual emissions from the dryers listed in this subsection 218.480(b)(4) shall not exceed 18,688 kg/year (20.6 tons/year). [BOARD NOTE: tunnel dryers are otherwise referred to as warm air dryers]; and
 - 45) For each Accelacota: 6,803 kg/year (7.5 tons/year).
- c) Sections 218.483 through 218.485 of this Part apply to a source having one or more emission units that:
- 1) Are used to manufacture pharmaceuticals, and
 - 2) Emit more than 6.8 kg/day (15 lbs/day) of VOM and more than 2,268 kg/year (2.5 tons/year) of VOM, or, if less than 2,268 kg/year (2.5 tons/year), these Sections still apply if emissions from one or more sources exceed 45.4 kg/day (100 lbs/day).
- d) No owner or operator shall violate any condition in a permit when the condition results in exclusion of an emission unit from this Subpart.
- e) Any pharmaceutical manufacturing source that becomes subject to the provisions of this Subpart at any time shall remain subject to the provisions of this Subpart at all times.
- f) Emissions subject to this Subpart shall be controlled at all times consistent with the requirements set forth in this Subpart.
- g) Any control device required pursuant to this Subpart shall be operated at all times when the source it is controlling is operated.
- h) Determinations of daily and annual emissions for purposes of this Section 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 Section 218.487 of this Part 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), incorporated by reference in Section 218.112 of this Part. (This subsection shall not affect the Agency's or the USEPA's authority to require emission tests to be performed pursuant to Section 218.487 of this Part.)

- i) Equipment and operations emitting VOM at a source subject to subsection (a) or (c) of this Section and used to produce pharmaceutical products or a pharmaceutical-like product such as a hormone, enzyme, or antibiotic, shall be deemed to be engaged in the manufacture of pharmaceuticals for the purposes of this Subpart.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

IT IS SO ORDERED.

Board Member Andrea S. Moore abstained.

Section 41(a) of the Environmental Protection Act provides that final Board orders may be appealed directly to the Illinois Appellate Court within 35 days after the Board serves the order. 415 ILCS 5/41(a) (2006); *see also* 35 Ill. Adm. Code 101.300(d)(2), 101.906, 102.706. Illinois Supreme Court Rule 335 establishes filing requirements that apply when the Illinois Appellate Court, by statute, directly reviews administrative orders. 172 Ill. 2d R. 335. The Board's procedural rules provide that motions for the Board to reconsider or modify its final orders may be filed with the Board within 35 days after the order is received. 35 Ill. Adm. Code 101.520; *see also* 35 Ill. Adm. Code 101.902, 102.700, 102.702.

I, John T. Therriault, Assistant Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above opinion and order on August 21, 2008, by a vote of 3-0.



John T. Therriault, Assistant Clerk
Illinois Pollution Control Board