

ILLINOIS POLLUTION CONTROL BOARD
October 4, 2007

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)))

Proposed Rule. First Notice.

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 Environmental Protection Act (Act) (415 ILCS 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. Abbott also filed motions requesting the Board to waive the requirement for 200 signatures on its petition and to expedite consideration of its request by, among other things, ordering immediate publication of the rules for first notice under the Illinois Administrative Procedure Act (APA) (5 ILCS 100/1-1)(2006). *See*, respectively, 35 Ill. Adm. Code Sections 102.202(g) and 101.512. To date, the Board has received no response to either motion from the Illinois Environmental Protection Agency (Agency) or any other person.

In this order, the Board accepts the proposal for hearing, granting the motion to waive signature requirement. The Board denies the motion for expedited consideration, but authorizes first-notice publication of the proposal without comment on the proposal's merits.

THE PROPOSAL

Abbott owns a pharmaceutical manufacturing facility located in Libertyville Township, Lake County, Illinois ("the Facility"). Abbott's operations are subject to 35 Ill. Adm. Code, Subpart T – Pharmaceutical Manufacturing ("Subpart T"). As currently written, Subpart T, Section 218.480(b) ("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 is proposing 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.

MOTIONS

Abbott first requests that the Board waive the requirement for 200 signatures on the petition, as required by 35 Ill. Adm. Code Section 102.202(g). In support of this motion, Abbott cites various past proceedings in which the Board has granted similar requests.

In its motion to expedite (Mot. Exp.), Abbott also requests that the Board proceed to APA first notice without reaching a decision on the merits, by accepting the regulatory language proposed by Abbott in this rulemaking proposal only for purposes of first notice. Abbott also requests that the requisite hearing be scheduled as soon as possible in accordance with Section 28(a) of the Act. Mot. Exp. at 2-3.

In support of this request, Abbott asserts that the proposal is intended to increase efficiency in its use of certain fluidized bed and tunnel dryers while providing for lower allowable emissions from these dryers as a group. Abbott contends that the current rule "requires Abbott to utilize its equipment and resources in a manner that is inefficient . . . [causing] material prejudice to Abbott." Mot. Exp. at 2. Abbott states that the Agency has been contacted and has no disagreement with the proposed amendments. Abbott also cites to other proceedings in which the Board has granted similar requests. Abbott also states that if more information is needed that it will expeditiously provide it. *Id.* at 3.

DISCUSSION

First, the Board finds that the petition meets the content requirements of 35 Ill. Adm. Code 102.208 and 102.210 and is accepted for hearing. However, a review of the proposal reveals that Abbott did not address the applicability of, or provide the information requested in, the "published study or report" requirement of Section 102.210(c). 35 Ill. Adm. Code 102.210(c); *see also* 35 Ill. Adm. Code 102.210(g). The Board requests that Abbott address Section 102.210(c), or its inapplicability, in writing, prior to any hearing scheduled in this proceeding or at such other time as directed by the hearing officer.

Next, the Board grants the motion to waive the signature requirement of Section 102.202(g).

Lastly, the Board denies the motion for expedited consideration. Requests for expedited review are governed by Section 101.512 of the Board's rules, and must contain, *inter alia*, a complete statement of the facts and reasons for the request. *See* 35 Ill. Adm. Code 101.512. In acting on a motion for expedited review, the Board considers, at a minimum, all statutory requirements and whether or not material prejudice will result from the motion being granted or denied. 35 Ill. Adm. Code 101.512(b). In addition, the Board will only grant a motion for expedited review consistent with available resources. *See* 35 Ill. Adm. Code 101.512(c).

The Board does not discount Abbott’s assertions that continued operations using less efficient drying processes is not optimal, and for the purposes of this motion accepts as true Abbott’s assertions that actual emissions would be lowered if it operates under an amended rule as proposed. However, this does not give rise to “material prejudice” sufficient to allow the Board to grant Abbott’s request as made.

As noted, expedited review is granted consistent with decision deadlines and available resources. The Board currently has numerous open rulemaking dockets that demand immediate attention, as well as pressing cases that will keep the Board busy for several months.

Due to attrition, Board staffing is at its lowest levels in some years. Even if the Board were to accept that Abbott’s claims amount to “material prejudice”, the Board’s limited resources in light of its current and future decision deadlines render the granting of a motion for expedited review unlikely in all but the most dire circumstances.

However, the Board can authorize the first-notice publication of this proposal without comment on its merits. The Board notes that it has made minor, non-substantive changes to the text of the proposed rule. The Board directs its hearing officer to expeditiously schedule hearing consistent with the Board’s decision calendar and operational needs.

The Board directs the Clerk to cause first-notice publication in the *Illinois Register* of the following proposed rule:

TITLE 35: ENVIRONMENTAL PROTECTION
 SUBTITLE B: AIR POLLUTION
 CHAPTER I: POLLUTION CONTROL BOARD
 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
218.448	Recordkeeping for Leaks
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
218.628	Leaks
218.630	Clean Up
218.636	Compliance Schedule
218.637	Recordkeeping and Reporting

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 SOCFI 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 31 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 18,779 kg/year (20.7 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 31 Ill. Reg. _____, effective _____)

IT IS SO ORDERED.

Member A. S. Moore abstained.

I, John T. Therriault, Assistant Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above order on October 4, 2007, by a vote of 3-0.



John T. Therriault, Assistant Clerk
Illinois Pollution Control Board