#### POLLUTION CONTROL BOARD

#### NOTICE OF PROPOSED AMENDMENT

1) <u>Heading of the Part</u>: Organic Material Emission Standards and Limitations for the IVED Chicago Area CLERK'S OFFICE

OCT 19 2007

2) <u>Code Citation</u>: 35 Ill. Adm. Code Part 218

STATE OF ILLINOIS
Pollution Control Board

3) Section Number:

Proposed Action:

218.480

Amend

- 4) <u>Statutory Authority</u>: Implementing Section 10 and authorized by Sections 27 and 28 of the Environmental Protection Act [415 ILCS 5/10, 27 and 28]
- A Complete Description of the Subjects and Issues Involved: For a more detailed 5) discussion of these amendments, see the Board's October 4, 2007 opinion and order in docket R08-8: Abbott Laboratories' Proposed Site Specific Amendment to Applicability Section of Organic Material Emission Standards and Limitations for the Chicago Area; Subpart T: Pharmaceutical Manufacturing (35 Ill. Adm. Code 218.480(b)) (R08-8). Abbott Laboratories proposed site-specific amendments for its pharmaceutical manufacturing facility located in Libertyville Township, Lake County. 35 Ill. Adm. Code 218.480(b) contains certain exemptions that are only applicable to Abbott's air suspension coater/dryer, fluid bed dryers, tunnel dryers, and Accelacotas. 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. In response to Abbott's request, the Board accepted the proposal for hearing, and first notice publication, but does not comment on the merits of the Abbott proposal.
- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None presently identified.
- 7) Will this proposed rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this proposed rulemaking contain incorporations by reference? No
- 10) Are there any other proposed amendments pending on this Part? No

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- 11) <u>Statement of Statewide Policy Objectives</u>: This proposed rule does not create or enlarge a State mandate, as defined in Section 3(b) of the State Mandates Act. [30 ILCS 805/3(b) (2006)]
- Time, Place, and Manner in which interested persons may comment on this proposed rulemaking: The Board is in the process of scheduling a hearing in the rulemaking. Additionally, the Board will accept written public comment on this proposal for 45 days after the date of publication in the *Illinois Register*. Comments should reference Docket R08-8 and be addressed to:

Clerk's Office Illinois Pollution Control Board 100 W. Randolph St., Suite 11-500 Chicago, IL 60601

Interested persons may request copies of the Board's opinion and order by calling the Clerk's office at 312/814-3620, or may download copies from the Board's Web site at www.ipcb.state.il.us.

For more information, contact hearing officer Kathleen M. Crowley at 312/814-6929 or email at crowlek@ipcb.state.il.us.

- 13) <u>Initial Regulatory Flexibility Analysis</u>:
  - A) Types of small businesses, small municipalities and not for profit corporations affected: This proposed rulemaking is site specific and will only impact Abbott Laboratories.
  - B) Reporting, bookkeeping or other procedures required for compliance: This rulemaking does not impose any additional reporting or recordkeeping requirements.
  - C) <u>Types of professional skills necessary for compliance</u>: No professional skills beyond those currently required by the existing state and federal air pollution control regulations applicable to affected source will be required.
- 14) Regulatory Agenda on which this rulemaking was summarized: The Board did not anticipate that Abbott Laboratories would request this site-specific relief.

## POLLUTION CONTROL BOARD

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The full text of the Proposed Amendment begins on the next page:

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| 4  |         | SUBCHAPTER c: EMISSIONS STANDARDS AND                                    |
| 5  |         | SUBCHAPTER c: EMISSIONS STANDARDS AND LIMITATIONS FOR STATIONARY SOURCES |
| 6  |         | DARTIONS FOR STATIONARY SOURCES  OCT 19 2007                             |
| 7  |         | PARI 218   |
| 8  |         | PART 218 ORGANIC MATERIAL EMISSION STANDARDS AND STATE OF ILLINOIS       |
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| 324        |         | SUBPART QQ: MISCELLANEOUS FORMULATION  |
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| 363                    | 218.APPENI     |            | Coefficients for the Total Resource Effectiveness Index (TRE) Equation     |
| 364                    | 218.APPENI     |            | List of Affected Marine Terminals  |
| 365                    | 218.APPENI     |            | TRE Index Measurements for SOCMI Reactors and Distillation Units           |
| 366                    | 218.APPENI     |            | Baseline VOM Content Limitations for Subpart F, Section 218.212            |
| 367                    | 210.241 12141  | 717111     | Cross-Line Averaging   |
| 368                    |                |            | Closs-Line Averaging   |
| 369                    | ATTTHODITY     | V. Imple   | menting Section 10 and authorized by Sections 27, 28, and 28.5 of the      |
| 370                    |                |            | tion Act [415 ILCS 5/10, 27, 28, and 28.5].                                |
| 370                    | Ellyllollllell | ai Fioleci | Holi Act [413 11C3 3/10, 27, 26, and 26.3].                                |
| 372                    | SOLIDOE: A     | donted a   | t R91-7 at 15 Ill. Reg. 12231, effective August 16, 1991; amended in R91-  |
| 373                    |                |            | 4, effective August 24, 1992; amended in R91-28 and R91-30 at 16 Ill.      |
| 373<br>374             |                |            | August 24, 1992; amended in R93-9 at 17 Ill. Reg. 16636, effective         |
| 37 <del>4</del><br>375 | _              |            |  |
|                        |                |            | mended in R93-14 at 18 III. Reg. 1945, effective January 24, 1994;         |
| 376                    |                |            | 18 Ill. Reg. 14973, effective September 21, 1994; amended in R94-15 at     |
| 377                    |                |            | ective October 25, 1994; amended in R94-16 at 18 Ill. Reg. 16950,          |
| 378                    |                |            | 5, 1994; amended in R94-21, R94-31 and R94-32 at 19 Ill. Reg. 6848,        |
| 379                    | _              |            | ; amended in R94-33 at 19 Ill. Reg. 7359, effective May 22, 1995;          |
| 380                    |                |            | 20 Ill. Reg. 14428, effective October 17, 1996; amended in R97-24 at 21    |
| 381                    |                |            | re June 9, 1997; amended in R97-31 at 22 Ill. Reg. 3556, effective         |
| 382                    |                |            | ended in R98-16 at 22 III. Reg. 14282, effective July 16, 1998; amended in |
| 383                    |                |            | 7283, effective April 8, 2003; amended in R04-12/20 at 30 III. Reg. 9684,  |
| 384                    |                |            | 6; amended in R06-21 at 31 III. Reg. 7086, effective April 30, 2007;       |
| 385                    | amended in R   | cus-s at 3 | 32 Ill. Reg, effective   |
| 386                    |                | OT TO      | DADTT. DUADAG CEUTICAL MANTEL COMPENS                                      |
| 387                    |                | SUE        | SPART T: PHARMACEUTICAL MANUFACTURING                                      |

| 388        |               |             |  |
|------------|---------------|-------------|--|
| 389        | Section 218.4 | 480 Ap      | pplicability   |
| 390        |               |             |  |
| 391        | a)            |             | ules of this Subpart, except for Sections 218.483 through 218.485 of this  |
| 392        |               |             | apply to all emission units of VOM, including but not limited to reactors,   |
| 393        |               | distil      | lation units, dryers, storage tanks for VOL, equipment for the transfer of   |
| 394        |               |             | , filters, crystallizers, washers, laboratory hoods, pharmaceutical coating  |
| 395        |               | -           | ations, mixing operations and centrifuges used in manufacturing, including   |
| 396        |               | -           | aging, of pharmaceuticals, and emitting more than 6.8 kg/day (15 lbs/day)  |
| 397        |               |             | nore than 2,268 kg/year (2.5 tons/year) of VOM. If such an emission unit   |
| 398        |               |             | s less than 2,268 kg/year (2.5 tons/year) of VOM, the requirements of this   |
| 399        |               | _           | art still apply to the emission unit if VOM emissions from the emission unit   |
| 400        |               | excee       | ed 45.4 kg/day (100 lbs/day).  |
| 401        |               |             |  |
| 402        | b)            |             | rithstanding subsection (a) of this Section, the air suspension coater/dryer,  |
| 403        |               |             | bed dryers, tunnel dryers, and Accelacotas located in Libertyville Township,   |
| 404        |               |             | County, Illinois shall be exempt from the rules of this Subpart, except for  |
| 405        |               |             | ons 218.483 through 218.485, if emissions of VOM not vented to air   |
| 406        |               | pollu       | tion control equipment do not exceed the following levels:   |
| 407        |               | 4.5         |  |
| 408        |               | 1)          | For the air suspension coater/dryer: 2,268 kg/year (2.5 tons/year);  |
| 409        |               | <b>a</b> \  |  |
| 410        |               | 2)          | Except as set forth in subsection (b)(4) of this Section, for For each fluid   |
| 411        |               |             | bed dryer: 4,535 kg/year (5.0 tons/year);  |
| 412        |               | 2)          | Encoderate Code in the discount of the first |
| 413        |               | 3)          | Except as set forth in subsection (b)(4) of this Section, for For each tunnel  |
| 414        |               |             | dryer: 6,803 kg/year (7.5 tons/year); and  |
| 415        |               | 4)          | For flyid had devices #1 #2 and #2 and for turn of devices #1 #2 #2 and  |
| 416        |               | <u>4)</u>   | For fluid bed dryers #1, #2, and #3 and for tunnel dryers #1, #2, #3, and  |
| 417<br>418 |               |             | #4, the combined total annual emissions from the dryers listed in this   |
| 410<br>419 |               |             | subsection (b)(4) shall not exceed 18,779 kg/year (20.7 tons/year); and  |
| 420        |               |             | BOARD NOTE: Tunnel dryers are otherwise referred to as warm air  |
| 420<br>421 |               |             | dryers.  |
| 422        |               |             | di yors.   |
| 423        |               | <u>5</u> 4) | For each Accelacota: 6,803 kg/year (7.5 tons/year).  |
| 424        |               | <u>2</u> 7) | Tot each Accelacota. 0,003 kg year (7.5 totis/year).   |
| 425        | c)            | Section     | ons 218.483 through 218.485 of this Part apply to a source having one or   |
| 425<br>426 | υ,            |             | emission units that:   |
| 427        |               | 111010      | VIIIIDDIVII MINID LIUL.  |
| 428        |               | 1)          | Are used to manufacture pharmaceuticals, and   |
| 429        |               | 1)          | The about to manufacture priminaceantents, and   |
| 430        |               | 2)          | Emit more than 6.8 kg/day (15 lbs/day) of VOM and more than 2.268  |

| 431 |       | kg/year (2.5 tons/year) of VOM, or, if less than 2,268 kg/year (2.5                   |
|-----|-------|---|
| 432 |       | tons/year), these Sections still apply if emissions from one or more sources          |
| 433 |       | exceed 45.4 kg/day (100 lbs/day).   |
| 434 |       |   |
| 435 | d)    | No owner or operator shall violate any condition in a permit when the condition       |
| 436 |       | results in exclusion of an emission unit from this Subpart.                           |
| 437 |       | •   |
| 438 | e)    | Any pharmaceutical manufacturing source that becomes subject to the provisions        |
| 439 | •     | of this Subpart at any time shall remain subject to the provisions of this Subpart at |
| 440 |       | all times.  |
| 441 |       |   |
| 442 | f)    | Emissions subject to this Subpart shall be controlled at all times consistent with    |
| 443 |       | the requirements set forth in this Subpart.   |
| 444 |       |   |
| 445 | g)    | Any control device required pursuant to this Subpart shall be operated at all times   |
| 446 | 8)    | when the source it is controlling is operated.  |
| 447 |       |   |
| 448 | h)    | Determinations of daily and annual emissions for purposes of this Section shall be    |
| 449 | )     | made using both data on the hourly emission rate (or the emissions per unit of        |
| 450 |       | throughput) and appropriate daily and annual data from records of emission unit       |
| 451 |       | operation (or material throughput or material consumption data). In the absence       |
| 452 |       | of representative test data pursuant to Section 218.487 of this Part for the hourly   |
| 453 |       | emission rate (or the emissions per unit of throughput), such items shall be          |
| 454 |       | calculated using engineering calculations, including the methods described in         |
| 455 |       | Appendix B of "Control of Volatile Organic Emissions from Manufacturing of            |
| 456 |       | Synthesized Pharmaceutical Products" (EPA-450/2-78-029), incorporated by              |
| 457 |       | reference in Section 218.112 of this Part. (This subsection shall not affect the      |
| 458 |       | Agency's or the USEPA's authority to require emission tests to be performed           |
| 459 |       | pursuant to Section 218.487 of this Part.)  |
| 460 |       | parameter decision and rainer   |
| 461 | i)    | Equipment and operations emitting VOM at a source subject to subsection (a) or        |
| 462 | -/    | (c) of this Section and used to produce pharmaceutical products or a                  |
| 463 |       | pharmaceutical-like product such as a hormone, enzyme, or antibiotic, shall be        |
| 464 |       | deemed to be engaged in the manufacture of pharmaceuticals for the purposes of        |
| 465 |       | this Subpart.   |
| 466 |       | min peoper.   |
| 467 | (Sour | rce: Amended at 32 Ill. Reg, effective)   |
|     | •     |   |

TITLE 35: ENVIRONMENTAL PROTECTION SUBTITLE B: AIR POLLUTION CHAPTER I: POLLUTION CONTROL BOARD SUBCHAPTER C: EMISSIONS STANDARDS AND LIMITATIONS FOR STATIONARY SOURCES PART 218 OCT 19 2007 ORGANIC MATERIAL EMISSION STANDARDS AND LIMITATIONS FOR THE CHICAGO AREA STATE OF ILLINOIS Pollution Control Board SUBPART A: GENERAL PROVISIONS Section 218.100 Introduction 218.101 Savings Clause
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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, and 28.5 of the Environmental Protection Act [415 ILCS 5/10, 27, 28, 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);
- Except as set forth in subsection 218.480(b)(4) of this Section, for Foreach 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): and

BOARD NOTE: tunnel tryers are otherwise referred to as warm air dryers and.

- 455) 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. | <br>effective | ) |
|----------|----------|----|----|------|------|---------------|---|
| TITINOTS | DECTOTED |    |    |      |      |               |   |

POLLUTION CONTROL BOARD

NOTICE OF PROPOSED AMENDMENT

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