

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

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

NOTICE OF FILING

| | |
|----------------------------------|----------------------------------|
| TO: Mr. John Therriault | Kathleen M. Crowley, Esq. |
| Assistant Clerk of the Board | Hearing Officer |
| Illinois Pollution Control Board | Illinois Pollution Control Board |
| 100 West Randolph Street | 100 West Randolph Street |
| Suite 11-500 | Suite 11-500 |
| Chicago, Illinois 60601 | Chicago, Illinois 60601 |
| (VIA ELECTRONIC MAIL) | (VIA U.S. MAIL) |

(PERSONS ON ATTACHED SERVICE LIST)

PLEASE TAKE NOTICE that I have today filed with the Office of the Clerk of the Illinois Pollution Control Board **ABBOTT LABORATORIES' POST-HEARING COMMENTS**, a copy of which is herewith served upon you.

Respectfully submitted,

By: /s/ Katherine D. Hodge
Katherine D. Hodge

Dated: May 1, 2008

Katherine D. Hodge
 Lauren C. Lurkins
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CERTIFICATE OF SERVICE

I, Katherine D. Hodge, the undersigned, hereby certify that I have served

ABBOTT LABORATORIES' POST-HEARING COMMENTS upon:

Mr. John Therriault
Assistant Clerk of the Board
Illinois Pollution Control Board
100 West Randolph Street
Suite 11-500
Chicago, Illinois 60601

via electronic mail on May 1, 2008; and upon:

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by depositing said document in the United States Mail, postage prepaid, in Springfield,
Illinois on May 1, 2008.

/s/ Katherine D. Hodge
Katherine D. Hodge

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ABBOTT LABORATORIES' POST-HEARING COMMENTS

NOW COMES ABBOTT LABORATORIES (“Abbott”), by and through its attorneys, HODGE DWYER ZEMAN, and hereby provides the Illinois Pollution Control Board (“Board”) with the following post-hearing comments.

I. BACKGROUND

On September 4, 2007, Abbott submitted to the Board a proposed site-specific amendment to 35 Ill. Admin. Code § 218.480(b) (“Section 218.480(b)”) pursuant to Sections 27 and 28 of the Illinois Environmental Protection Act (“Act”) (415 ILCS 27 and 28), 35 Ill. Admin. Code § 102.210 and 35 Ill. Admin. Code § 102.202(b) to allow it “additional operational flexibility” with regard to emissions from certain tunnel dyers and fluid bed dyers at its pharmaceutical manufacturing facility located in Libertyville Township, Lake County, Illinois (“Facility”). As part of its initial filing, Abbott also submitted motions requesting the Board to waive the requirement for 200 signatures on its proposal 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).

On October 4, 2007, the Board issued its First Notice Opinion and Order accepting the proposal for hearing and granting Abbott's Motion to Waive Requirement to Submit 200 Signatures. In the same Opinion and Order, the Board denied Abbott's Motion for Expedited Review, but authorized first-notice publication without comment on the merits of the proposal.

On February 22, 2008, Abbott submitted the Prefiled Testimony of Diane Beno in Support of Proposed Site-Specific Amendment and the Prefiled Testimony of Robert C. Wells in Support of Proposed Site-Specific Amendment. On February 29, 2008, Abbott filed its Motion to File Revised Exhibit 3 and Minor Revision to Proposed Subsection 218.480(b)(4), in which Abbott sought to make the following changes to Exhibit 3¹ that was submitted with the proposal: 1) correct a typographical error for the 1999 total, changing 26.1 to 25.1; 2) show single-unit data at 2 decimal places; 3) add a line for 90% of the baseline, with the corrected value of 20.6 tons per year; 4) add Note c to identify the round-off issue and specify that totals are correct based on calculations with more significant figures; and 5) update the reference in Note a to reflect the correct condition in the renewed Clean Air Act Permit Program ("CAAPP") Permit, issued on September 26, 2007. Abbott also sought to file a minor revision to its proposed amendment Section 218.480(b) to reflect the change made to the 90% baseline calculations, as follows:

¹ Please note that one additional clarification may be needed for the revised Exhibit 3. Specifically, upon compilation of the emission calculation data requested by USEPA and Illinois EPA after the hearing in this matter, it was noted that one small run with VOM emissions was conducted in fluid bed dryer # 3 in July of 1999. This run resulted in 0.0326 tons (65 pounds) of VOM emissions. These emissions were not included in the revised Exhibit 3 due to the rounding of values in the original Exhibit. The additional 65 pounds of emissions do not change the indicated total 1999 emissions, the 2-year emission total, or proposed combined limit for the seven dryers (90 percent of baseline), which are each stated to the nearest 0.1 ton per year in revised Exhibit 3.

- 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~~ **18,688** kg/year (~~20.7~~ **20.6** tons/year). [BOARD NOTE: tunnel dryers are otherwise referred to as warm air dryers]; and

* * *

A hearing was held in Libertyville on March 7, 2008 (“Hearing”), with representatives of both the Illinois Environmental Protection Agency (“Illinois EPA”) and Abbott in attendance.

II. THE PROPOSAL

As explained more fully in Abbott’s proposal and at the Hearing, Abbott produces numerous pharmaceutical products at the Facility, and these operations are subject to 35 Ill. Admin. Code Subpart T – Pharmaceutical Manufacturing (“Subpart T”). As currently written, Section 218.480(b) of Subpart T 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 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 these dryers based on their actual combined emissions. If adopted, the proposed amendment would reduce the overall allowable emissions from these units while increasing Abbott’s operational flexibility with regard to these units.

III. DISCUSSION

The following information was presented at Hearing in direct testimony and in response to questions of the Board. Abbott presented two witnesses: Diane Beno, the

plant manager at Abbott's Building AP16; and Robert C. Wells, Air Manager for Environmental Support in Abbott's Global Environmental Health & Safety Department. Illinois EPA presented one witness: Yoginder Mahajan, an Engineer with the Air Quality Planning Section of the Illinois EPA Bureau of Air.

A. Facility Process and Affected Emission Units

In Building AP16 at the Facility, Abbott produces intermediate and final pharmaceutical product formulations. Pre-Filed Testimony of Diane Beno ("Beno") at 1. Abbott manufactures its products using batch production processes. Beno at 2. In batch production, all of the processing equipment in a process train, including the dryers, manufactures one product at a time. Beno at 2. In a typical process, the active and inactive ingredients are combined with a liquid in a process called "massing." Beno at 2. This massing process forms uniform granules. Beno at 2. The 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. Beno at 2. If an organic solvent is volatilized from the dryer, it is emitted to the ambient air as volatile organic material ("VOM") or volatile organic compounds. Beno at 2. The quantity of VOM emissions will vary 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 CAAPP Permit for the Facility. Beno at 2.

As stated above, Abbott's proposed site-specific amendment covers four tunnel dryers and three fluid bed dryers. Beno at 3. 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. Beno at 3.

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. Beno at 3. 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. Beno at 3. Abbott anticipates increased use of water for the massing fluid in future products. Beno at 3. Abbott expects that this preferential use of fluid bed dryers and water-based products will continue. Beno at 3.

Batches of specific products are typically manufactured using either one or more tunnel dryers, or one or more fluid bed dryers, but not both, because the technologies are not interchangeable. Beno at 3. Individual dryers of the same type can typically be used in combination or interchangeably in many cases, but specific dryers are preferable for combining with other equipment in a process train to manufacture certain products from an operational efficiency standpoint. Beno at 3-4.

Process trains are designed to accommodate batches of different scales, with some for large batches and others for small batches. Beno at 4. Therefore, the scale of a given batch plays an important role in determining which of the dryers will be most efficient. Beno at 4. Additionally, extensive equipment cleaning is required between batches of different products, resulting in up to three days of lost production time. Beno at 4. Therefore, Abbott uses a campaign strategy to continue running batches of the same product consecutively in the process train to minimize this cleaning time. Beno at 4.

As currently written, Section 218.480(b) effectively defines a 12-month total VOM limit on each individual dryer. Beno at 4. To ensure compliance with the current running 12-month total VOM limit on each dryer, for a particular batch, Abbott may be required to utilize a dryer with low VOM emissions during the last 12 months instead of using the dryer that is the most efficient from a production-scale standpoint. Beno at 4. Additionally, the dryer selected for a given campaign also depends on dryer availability and other factors. Beno at 4-5. Therefore, the standards, as currently defined, can result in wasted resources by requiring Abbott to dry a small batch of product in our large-scale process train to maintain our equipment-specific VOM limits. Beno at 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. Beno at 5. The assignment of a campaign of a particular product to one or more dryers involves a number of operating factors, such as scale and equipment availability, that contribute to the efficiency of manufacturing. Beno at 5. The VOM emission threshold effectively acts as an overriding factor that can force a particular production campaign with VOM emissions to be scheduled using equipment that has low enough recent emissions to avoid exceeding a dryer threshold, but that may not otherwise be the optimal or most efficient equipment for the campaign. Beno at 5. This scheduling shift 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 optimal equipment. Beno at 5.

In order to ensure Abbott's Facility remains competitive with its national and global competitors, Abbott must continually seek ways of making its manufacturing operations more efficient. Beno at 5. The scheduling inefficiency created by Subpart T

was identified as one area where improvements in efficiency could be made and is the basis for the proposed amendment. Beno at 5.

The most efficient method to manufacture Abbott's products in Building AP16 would be to use the dryer that is best suited to the requirements of the production schedule and scale, regardless of the amount of VOM that has been emitted from that dryer in the past 12 months. Beno at 6. Provided that the combined VOM emissions from all of the dryers are less than the combined amount allowed under Section 218.480(b), this method of operation would not require an increase in allowable VOM emissions from the Facility. Beno at 6. In fact, the proposed amendment would provide Abbott improved production flexibility to utilize the most efficient dryers for a given product, while significantly lowering the total allowed VOM emissions from all the dryers combined. Beno at 6.

B. Applicable Requirements and Actual Emissions

Subpart T requires VOM controls for tunnel dryers and fluid bed dryers if the annual emissions exceed 7.5 tons per year ("ton/yr") for a tunnel dryer or 5 ton/yr for a fluid bed dryer. Hearing Transcript ("Tr.") at 25. The four tunnel dryers and three fluid bed dryers at issue in this proceeding, therefore, have total potential emissions without control of 45 ton/yr. Tr. at 25. Because of the cost associated with VOM control for this type of equipment, it is impractical to add control. Tr. at 25. Thus, the limits applicable before control is required effectively act as upper limits on the air emissions from the seven dryers. Tr. at 25. The actual emissions from the seven dryers vary year to year based on the quantity of production and the different materials produced. Tr. at 25. In recent years, Abbott's tunnel dryer emissions have varied from 0.6 ton/yr to 5.6 ton/yr

each year. Tr. at 25-26. Fluid bed dryer emissions have varied from 0.1 ton/yr to 3.9 ton/yr each year the dryers have been operating. Tr. at 26.

C. Economic Incentive Program

Abbott discussed alternative solutions to eliminate manufacturing constraints that affected the efficiency of the overall operation with Illinois EPA and USEPA. Tr. at 27. Illinois EPA and USEPA identified an alternative that was preferable to them called a Source Specific Emissions Cap (“SSEC”) Economic Incentive Program (“EIP”), as identified in the USEPA Office of Air and Radiation’s EIP guidance document entitled Improving Air Quality with Economic Incentive Programs, Doc. No. EPA-452/R01-001 (January 2001). Tr. at 27. The SSEC would allow Abbott to combine its future emission limits for all the dryers and establish a limit below the historical actual emissions, rather than the previously allowable emissions or emissions allowable without control. Tr. at 27. Under such an approach, the historical emissions would be based on a concept called “baseline actual emissions,” which is defined as the highest two-year period in the preceding ten-year period. Tr. at 27-28. Abbott reviewed the actual emissions from the dryers in the most recent ten years and identified the maximum two-year period with emissions of 22.9 ton/yr in 1999 and 2000. Tr. at 28. That amount was then reduced by ten percent to ensure environmental benefit and resulted in an emission limit of 20.6 ton/yr for the seven dryers. Tr. at 28. This emissions limit would be less than half of the 45 ton/yr effective limit that now applies to the seven dryers taken together. Tr. at 28. The significantly lower allowable limit is acceptable to Abbott’s anticipated business and meets its flexibility needs. Tr. at 28.

In going forward with the SSEC EIP approach, Abbott considered its conformance with the three general principles of an EIP: 1) integrity; 2) equity; and 3) environmental benefit. Tr. at 28-29. Abbott is confident that its proposal satisfies all of the general EIP principles. Tr. at 29-30.

D. Questions of the Board Addressed at Hearing

No members of the public attended the Hearing. Tr. at 4. At the Hearing, the Hearing Officer asked Abbott to address the questions of the Board that were included in the Hearing Officer Order of March 4, 2008. Tr. at 31. In response to those questions, the following testimony was provided by Abbott for the Board's consideration.

The Board's Statement of Reasons Question 1(a) referred to whether the information presented in the R86-10 rulemaking regarding economic feasibility of controlling emissions from Abbott's tunnel dryers and fluid bed dryers is still valid. In response, Mr. Wells stated that it is. Tr. at 31. As part of the rulemaking process, Abbott analyzed the cost of control using a methodology developed by USEPA for the Best Available Control Technology ("BACT") analysis. Tr. at 32. Using the BACT analysis, Abbott found that the cost of control continued to be significantly in excess of what is normally considered Reasonably Available Control Technology. Tr. at 32. Essentially, the economics have not changed since the R86-10 rulemaking. Tr. at 32.

Statement of Reasons Question 1(b) asked whether there has been any development in emissions control technology since the adoption of the original rules. In response, Mr. Wells stated that there have been no fundamental changes in emission control technology that would be applicable to the Facility since the original rulemaking.

Tr. at 32. Therefore, Abbott considered the same control technologies that were considered at the time of the original rulemaking. Tr. at 32.

Statement of Reasons Question 2(a) asked about the reasons for the significantly lower actual emissions from Abbott's dryers since year 2000. In response, Ms. Beno stated that pharmaceutical manufacturing business activity is highly variable year after year. Tr. at 32. The types of products Abbott produces in a given year can vary based on a number of market factors and patient demand. Tr. at 32-33. Different products emit different levels of VOM, and product mix is a primary factor regarding the variability of Abbott's emissions. Tr. at 33. Additionally, new products that have been introduced to the Facility typically have used water-based solvents, and there is no VOM produced when water is used as a massing fluid. Tr. at 33. Abbott also does not expect emissions to increase over time. Tr. at 33.

Statement of Reasons Question 2(b) asked whether Abbott has stopped operating dryer #4. In response, Ms. Beno stated that tunnel dryer #4 has not been in use since 2005. Tr. at 35. However, it remains fully validated, maintained and available for use should production needs demand. Tr. at 35.

Beno Prefiled Testimony Question 1 asked whether Abbott has used organic solvents other than ethanol in the manufacture of pharmaceuticals in the past. In response, Ms. Beno stated that ethanol has been the only organic massing fluid used by Abbott in Building AB16 during the ten-year period under review for the proposal. Tr. at 37. In late 2002, however, the type of ethanol used was denatured ethanol, which contains a small percentage of methanol as the denaturant. Tr. at 38. Since late 2002,

Abbott has converted to all beverage grade ethanol which does not contain methanol as the denaturant. Tr. at 38.

Beno Prefiled Testimony Question 2 asked for explanation of the basis for choosing the type of solvent used as massing fluid by Abbott. In response, Ms. Beno stated that the choice of massing fluid is dependent on the particular properties of a product, not whether or not water is an option. Tr. at 38. The type of dryer used also has nothing to do with the choice of solvent. Tr. at 38-39. Water or ethanol can be used in either drying technology. Tr. at 39.

Beno Prefiled Testimony Question 3(a) asked for comment on whether Abbott anticipates increased use of water in product lines using both tunnel dryers and fluid bed dryers. In response, Ms. Beno stated that Abbott does expect there to be an increased use of water in new products. Tr. at 39. However, it is not practical to change the ethanol-based processes to water-based processes because of United States Food and Drug Administration ("FDA") considerations. Tr. at 39. Abbott considers the type of massing fluid as it develops new products, with a preference to use water. Tr. at 39.

Beno Prefiled Testimony Question 3(b) asked whether the anticipated increase in use of water for massing fluid is intended to reduce VOM emissions. In response, Ms. Beno stated that VOM emission avoidance is one of several factors considered by Abbott as the benefits resulting from increased use of water for the massing fluid. Tr. at 39-40. Other benefits include increased raw material costs, reduced worker exposure to organic materials in the work place, and improved safety due to reduction of flammable solvents. Tr. at 40.

Beno Prefiled Testimony Question 3(c) asked why Abbott considers water-based products a “preferential use.” In response, Ms. Beno stated that water-based products are preferable for a number of reasons. Tr. at 40. They are preferable because they do not contribute to VOM emissions, reduced raw material costs, reduced worker exposure, and improved overall safety to the facility. Tr. at 40.

Beno Prefiled Testimony Question 4(a) asked how the fluid bed dryers are more efficient than the tunnel dryers. In response, Ms. Beno stated that fluid bed dryers are more efficient mainly due to their operation. Tr. at 40. In a fluid bed dryer, individual granules of product are airborne in the warm air stream and the air moves freely on all surfaces of the granule in the drying process. Tr. at 40. This results in a much more even drying process and higher quality end-product because of the evenness of the drying. Tr. at 41. Tunnel dryers, on the other hand, are similar to cookie sheets in an oven. Tr. at 41. Material is hand-loaded onto the sheet and onto a large rack. Tr. at 41. The rack is then pushed into the tunnel dryer and is exposed to air movement in the tunnel. Tr. at 41. The result in a tunnel dryer is similar to that found in baking: some parts of the product are more done than other parts. Tr. at 41. Whereas in the fluid bed drying technology, more of the product or granules are exposed to the warm air across the entire surface, making for a much more uniform drying process.²

Beno Prefiled Testimony Question 4(b) asked whether Abbott has any plans to replace the tunnel dryers with fluid bed dryers. In response, Ms. Beno stated that Abbott does not expect to phase out tunnel drying equipment or concentrate on purchasing new

² This is a correction from the Hearing Transcript at 41.

fluid drying equipment because switching technologies can have an impact on the safety and efficacy of a drug product and involve the FDA. Tr. at 34.

Beno Prefiled Testimony Question 5(a) asked what was meant by “using the dryer that is most efficient from a production-scale standpoint.” In response, Ms. Beno pointed out that one example of the inefficiencies created by the current rule is that the most appropriately sized equipment may not be chosen. Tr. at 41. In the event that the small-scale process train would be approaching its limit, Abbott may be forced to use the large-scale process train to process smaller batches than would normally be processed in that process train. Tr. at 42. In such a situation, the full capacity of the equipment would not be utilized. Tr. at 42.

Beno Prefiled Testimony Question 5(b) asked for factors, other than a dryer’s previous 12-month VOM emissions, that are considered in deciding the type of dryer to use for a particular campaign. In response, Ms. Beno stated that technology is considered first when making such a selection. Tr. at 43. As noted above, a product can be produced either by a tunnel dryer or a fluid bed dryer, not a combination. Tr. at 43. The second consideration is scale, meaning whether it is a small-scale batch or a large-scale batch. Tr. at 43. The third consideration is general availability, meaning whether Abbott has more products running in a certain scale or if one is down for maintenance or cleaning. Tr. at 43.

Wells Prefiled Testimony Questions 1 asked about whether the definition of “historical actual emissions” used in Mr. Wells’ prefiled testimony is based on USEPA’s EIP guidelines. Wells Prefiled Testimony Question 2(a) asked why the baseline was not calculated based on the average emissions of the past two years. Wells Prefiled

Testimony Question 2(b) asked why emissions from 1999 and 2000 were considered representative. In response to these questions, Mr. Wells stated that there has been a change in the philosophy on the conceptual level in USEPA's application of historical emissions. Tr. at 44. The definition of "historical actual emissions" that appears in the 2001 guidelines developed by USEPA is the same as the concept in the Prevention of Significant Deterioration ("PSD") or non-attainment New Source Review ("NSR") netting that USEPA has previously used and was in place at that time. Tr. at 44-45. That definition of "historical actual emissions" referred to the two years immediately preceding the action or another two-year period, if it could be determined more representative. Tr. at 45. Historically, there were a number of problems with determining whether a particular period was representative, so USEPA changed the definition of actual emissions in 2002. Tr. at 45. At that time, USEPA defined a term called "baseline actual emissions" for the PSD and NSR program that allowed the use of any 24-month period during the preceding 10 years. Tr. at 45. The new definition assures that a facility can look back far enough to find a representative business cycle so that it can locate periods when normal fluctuation of business would result in relatively higher emissions. Tr. at 45. Illinois EPA and USEPA recommended this new interpretation to Abbott. Tr. at 45-46. The baseline actual emissions were established in a Federal Register notice amending the PSD rules at 67 Fed. Reg. 80,186. Tr. at 46. Even though the VOM emissions from 1999 and 2000 are at least twice as much as the emissions from the next five years, Abbott chose 1999 and 2000 as representative because if it were to experience the same demand it did during those years and if it would have to use the same drying system or massing fluid, it would want to be able to fulfill

the demand. Tr. at 47. Additionally, Abbott reduced the historical baseline from 1999 and 2000 by ten percent. Tr. at 47. Overall, if Abbott ran all its dryers at capacity, it would produce 45 ton/yr, and the proposed regulatory relief would reduce that by more than half. Tr. at 47-48.

Proposed Amendment Question 1 asked whether the rules at Section 218.480(b) should state that the VOM limits apply to dryers located at the Abbott Laboratories, Building AP16, since the proposed amendments to Section 218.480(b)(4) refer specifically to certain numbered fluid bed dryers and tunnel dryers. In response, Mr. Wells stated that Abbott's concern with the specification of the equipment was that Section 218.480(b) now covers the entire Facility. Tr. at 50. Abbott would not have a problem if the specification were not made on the SSEC. Tr. at 50. With regard to Section 218.480(b)(4) specifically, it is Abbott's understanding that the general applicability of Section 218.480(b) still applies to the Facility. Tr. at 50. It is possible that Abbott might find the need to install a fluid bed dryer in another building for a totally unrelated manufacturing process, and thus, prefers this flexibility. Tr. at 50-51. Therefore, Abbott is comfortable with the way the rule is currently proposed. Tr. at 51. Abbott also has no objection to identifying the company in the rule. Tr. at 51.

Illinois EPA provided the following testimony to address the questions of the Board regarding USEPA's EIP guidance that were included in the Hearing Officer Order dated March 4, 2008.

The Board's USEPA EIP Guidance Question 1(a) asked whether the USEPA guidance implies that a state should first adopt some type of discretionary EIP policy before considering a request such as the one Abbott has made. In response, Mr. Yoginder

Mahajan of Illinois EPA's Air Quality Planning Section of the Bureau of Air stated that he spoke with Mr. Steve Rosenthal of USEPA and was told that state adoption of an EIP policy is recommended, but not required. Tr. at 49. Mr. Mahajan also noted that Illinois EPA does not intend to adopt such a policy, but instead, prefers to deal with the issue on a case-by-case basis. Tr. at 49.

USEPA EIP Guidance Question 2 asked whether Illinois EPA believes that the proposed rule and its supporting documentation satisfies EIP principles. In response, Mr. Mahajan stated that Illinois EPA discussed the issue with USEPA and confirmed that this amendment is consistent with the EIP guidelines. Tr. at 49.

USEPA EIP Guidance Question 3(a) asked whether the SSEC elements are those described under Section 4.1(b) of the guidance on page 38. In response, Mr. Mahajan confirmed they are. Tr. at 49.

USEPA EIP Guidance Question 3(b) asked whether there is any concern that the proposed combined VOM limit may not be consistent with the EIP guidelines since the baseline is calculated on the basis of highest actual emissions. In response, Mr. Mahajan stated that Illinois EPA had no concern. Tr. at 49. Illinois EPA discussed the issue with USEPA, and it was confirmed that the proposed combined VOM limit was consistent with the EIP guidelines. Tr. at 49.

Finally, Illinois EPA indicated its support for the rulemaking. Tr. at 54.

E. Economic and Budgetary Information

At the Hearing, counsel for Abbott addressed the issues regarding economic and budgetary effects raised by the Board in the January 31, 2008 Hearing Officer Order. The proposed rule will, if adopted by the Board, apply only to specific emission units

within Abbott's facility. 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 upon Illinois EPA, so there will be no budgetary effect. In light of the limited and site-specific nature of the proceeding, and the information set forth in Abbott's proposal and in Abbott's testimony presented at the Hearing, Abbott believes there is sufficient information in this record for the Board to make an analysis of the economic and budgetary effects of Abbott's proposal. Tr. at 9-10.

IV. ADDITIONAL INFORMATION PROVIDED TO THE BOARD

At the Hearing, counsel for Abbott noted that USEPA, through Illinois EPA, had requested that Abbott submit to USEPA supporting emissions calculations for the baseline years, 1999 and 2000. Tr. at 52. Since that time, Abbott has provided the requested information to both Illinois EPA and USEPA.³

V. SITE-SPECIFIC AMENDMENT TO SECTION 218.480(b) IS PROPER

The testimony at the Hearing demonstrated that Abbott has worked closely with Illinois EPA and USEPA over the course of the last several years, and Illinois EPA has stated that it supports the rulemaking. Tr. at 54. The amendment groups the VOM emissions from the dryers for the purpose of meeting the emission requirements for the exemption from portions of Subpart T and allows Abbott greater flexibility in its manufacturing process. The proposal would lower, by 24.3 ton/yr, the total amount of VOM that is allowed to be emitted by the affected dryers pursuant to the Subpart T

³ Abbott provided annual summaries of the 1999 and 2000 dryer VOM emissions in an April 23, 2008 e-mail to Mr. Matoesian and Mr. Mahajan of Illinois EPA and Mr. Rosenthal of USEPA. And, in discussions with counsel for Illinois EPA, Abbott has confirmed that there is no requirement (for SIP submittal purposes) to include this additional information in the Board record in this matter.

exemption. Further, the proposed amendment would allow Abbott to utilize the most efficient process unit for each batch process, irrespective of recent past usage of specific equipment. Finally, Illinois EPA supports this rulemaking. Tr. at 54.

VI. PROPOSED LANGUAGE

Abbott proposes that Section 218.480(b) be amended as follows:

- 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) below, 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) below, 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).

VII. CONCLUSION

WHEREFORE, based upon all the evidence that has been presented to the Illinois Pollution Control Board, the requirements of Sections 27 and 28 of the Act (415 ILCS 5/27 and 28), 35 Ill. Admin. Code § 102.210 and 35 Ill. Admin. Code § 102.202(b) have been satisfied in this proceeding. ABBOTT LABORATORIES, therefore, respectfully

requests that the Illinois Pollution Control Board adopt the proposed amendments to 35 Ill. Admin. Code § 218.480(b). ABBOTT LABORATORIES also respectfully asks the Board to expeditiously proceed to APA second notice in this matter.

Respectfully submitted,

ABBOTT LABORATORIES,

By: /s/ Katherine D. Hodge
One of its Attorneys

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ABOT:003/Filings/Post-Hearing Comments