

**MAR - 4 2008**

**STATE OF ILLINOIS**  
**Pollution Control Board**

ILLINOIS POLLUTION CONTROL BOARD  
March 4, 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))

**HEARING OFFICER ORDER**

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 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 (the Facility) located in Libertyville Township, Lake County.

As explained in the January 31, 2008 hearing officer order, the hearing in this rulemaking will be held in Libertyville on March 7, 2008, beginning at 1:00 p.m. Both the technical justification and economic impact of the rules will be addressed at this hearing, as the Board presently does not intend to schedule another hearing. *See* Section 27 (b) of the Act, 415 ILCS 5/27(b) (2006) and Section 102.414 of the Board's procedural rules, 35 Ill. Adm. Code 102.414.

On February 22, 2008, consistent with the hearing officer order, Abbott prefiled testimony of Diane Beno and Robert C. Wells. The Illinois Environmental Protection Agency (Agency) has not prefiled any testimony. No other testimony has been prefiled.

In the interest of facilitating the hearing process, the Board has reduced to writing questions it would like the participants to address at hearing, and is making them available to participants in advance of hearing. These questions appear on pages 2-5 of this order. While some questions are addressed to particular witnesses, any participant is free to address any of the questions.

The hearing officer has today telephoned counsel for Abbott and the Agency to advise them of issuance of this order. The Board's Clerk's Office is placing this order on the Board's website today, and is advising counsel who have filed appearances of its availability. This order will also be served on all parties on the notice list for this proceeding.

## **Questions on Proposal & Pre-filed Testimony**

### **Statement of Reasons**

1. On page 3, the Statement of Reasons (SOR) states that the current VOM requirements at Section 218.480(b) are based on the provisions of Section 215.480(b), which was adopted by the Board on April 7, 1988 in Docket R86-10. Further, the SOR states that during the rulemaking in R86-10 both the petitioner and IEPA “provided technical documentation and testimony to the effect that certain emission sources, including tunnel dryers and fluid bed dryers, would be economically infeasible to control at the levels required for certain other emission sources at the facility.”
  - a) Please comment on whether the information/testimony presented in the R86-10 rulemaking regarding economic feasibility of controlling emissions from Abbott’s tunnel dryers and fluid bed dryers is still valid.
  - b) Has there been in any development in emissions control technology since the adoption of the original rules that addresses the economic concerns associated with control of emissions from the affected dryers?
2. On page 6, the SOR notes that the average actual emissions from the fluid bed dryers and tunnel dryers for 1999 and 2000 were used to determine the proposed combined emission limit of 20.7 tons per year. (This was revised to 20.6 tons per year in Abbott’s February 29, 2008 motion to amend.) According to Exhibit 3, total emissions from years 1999 and 2000 represent the highest actual emissions. Starting from 2001 and until 2007, the total actual emissions from the affected dryers are approximately half the total emissions in 1999 and 2000. Further, the VOM emissions data show a declining trend.
  - a) Please explain the reasons for the significantly lower actual emissions from the dryers since year 2000.
  - b) The amended Exhibit 3 indicates that tunnel dryer #4 has zero VOM emissions since 2005. Please explain whether Abbott has stopped operating dryer #4.

### **Prefiled Testimony – Diane Beno**

1. On page 2, you state that the organic solvent currently used for massing fluid in AP-16 is ethanol. Please comment on whether Abbott has used organic solvents other than ethanol in the manufacture of pharmaceuticals in the past. If so, please provide names of other solvents used for massing fluid.
2. Please explain the basis for choosing the type of solvent used for massing fluid, i.e. whether the solvent type is mainly dependent on the product being manufactured or the type of solvent is also dependent on the type of dryer being used in the process.

3. On page 3, you state that Abbott has increased the use of fluid dryers for recently developed products, and anticipates increased use of water for the massing fluid.
  - a. Please comment on whether Abbott anticipates increased use of water in product lines using both tunnel dryers and fluid bed dryers.
  - b. Is the anticipated increase in use of water for massing fluid intended to reduce VOM emissions? If so, have you made any estimates of the amount of VOM reductions that may result from increased use of water?
  - c. Please elaborate on why Abbott considers water-based products as a “preferential use”.
  - d. Please explain what role, if any, pollution prevention (PP) plays in increasing the use of water for massing fluid in future products. Does Abbott have some type of an in-house PP incentive program to reduce VOM emissions? Please elaborate on Abbott’s PP activities as they may relate to the affected dryers.
4. Also on page 3, you note that increased use of fluid dryers is mainly because they are more efficient and produce a more uniform product than tunnel dryers.
  - a. Please explain how the fluid bed dryers are more efficient than the tunnel dryers.
  - b. Does Abbott have any plans to replace the tunnel dryers with fluid dryers?
5. On page 4, you state that under the current rules, Abbott may be required to utilize a dryer with low VOM emissions during the last 12 months instead of using the dryer that is most efficient from a production-scale standpoint to ensure compliance with the current running 12-month total VOM limit on each dryer.
  - a. Please clarify what you mean by “using the dryer that is most efficient from a production-scale standpoint.”
  - b. Other than a dryer’s previous 12-month VOM emissions, what factors are considered in deciding the type of dryer used for a particular campaign?

#### **Prefiled Testimony – Robert Wells**

1. On page 5, you state that under USEPA guidelines, “historical actual emissions” are defined as the highest actual emissions from any 2-year period within the last 10 years of operation. Please clarify whether the definition of “historical actual emissions” used in your testimony is based on the USEPA’s Economic Incentive Program (EIP) guidelines. If not, please provide a complete citation to the appropriate USEPA publication, which defines what constitutes historical actual emissions.

2. The USEPA's EIP guidelines at page 166 defines "historical actual emissions" as "actual emissions associated with a source in a time period prior to the source's participation in EIP, usually representing the average emissions of the past two years or some other more representative period."
  - a. Please explain why the baseline was not calculated on the basis of average emissions of the past two years (2006 & 2007).
  - b. If the basis for using the average emissions from 1999 and 2000 is because that period is more representative, please explain why that time period is considered representative. Particularly, since the emissions data indicate significantly lower emission during 2001 to 2005.

### **USEPA's Economic Incentive Program Guidance**

1. At page 3, the EIP guidance states that the guidance applies if a state or tribe wants to establish a discretionary EIP for attaining or maintaining the national ambient air quality standards (NAAQS) for criteria pollutants. Further, the guidance notes that any government agency with the authority to administer a SIP or TIP may adopt a discretionary EIP.
  - a. Does the above statement imply that the state should first adopt some type of a discretionary EIP policy before considering a request such as the one made by Abbott?
  - b. If so, has the Agency adopted an EIP policy for Illinois? If not, should this rulemaking be considered as the State's adoption of the EIP policy?
  - c. Please comment on whether Abbott's proposal is the first request made under the USEPA's EIP in Illinois.
2. At page 6, Mr. Wells states that in order to ensure that the proposed site-specific amendment is consistent with USEPA EIP guidance, and to realize the administrative benefit of a program, the program must satisfy three fundamental principles of USEPA's EIP program: integrity, equity and environmental benefit. Does the Agency believe that the proposed rule along with the supporting documentation satisfies the EIP principles?
3. At page 6 of Mr. Wells' testimony, Mr. Wells states that the principle of integrity consists of four elements: emissions must be surplus, quantifiable, enforceable, and permanent. Further he notes that these terms have specific meanings, and are different for a source specific emissions cap (SSEC) than for other programs addressed by the policy.
  - a. Please clarify whether the SSEC elements are those described under Section 4.1(b) of the guidance at page 38.

- b. Regarding emissions being surplus, is there any concern that the proposed combined VOM limit may not be consistent with the EIP guidance since the baseline is calculated on the basis of highest actual emissions?

**Proposed Amendments**

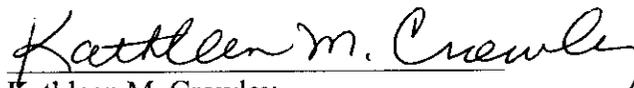
1. Abbott's proposal amends the existing rules at 35 Ill. Adm. Code 218.480(b), which sets forth that the VOM limits apply to air suspension dryers, fluid bed dryers, tunnel dryers, and Accelacotas located in Libertyville Township, Lake County, Illinois. Please comment on whether the rules should specifically state that the VOM limits apply to dryers located at the Abbott Laboratories, Building AP16, especially since the proposed amendments at Section 218.480(b)(4) refer specifically to certain numbered fluid bed dryers, and tunnel dryers.

**Abbot's February 29, 2008 Motion to Amend**

This order does not address Abbott's February 29, 2008 motion to amend Exhibit 3 as well as the text of its proposal. This motion is better addressed at hearing.

Again, at the close of hearing, the hearing officer will set a date by which the record will close and all public comments must be submitted. See 35 Ill. Adm. Code 102.108. As the Board is aware that Abbott would appreciate Board decision making as soon as possible, the posthearing comment period will not be lengthy unless unanticipated circumstances dictate otherwise.

IT IS SO ORDERED.

  
Kathleen M. Crowley  
Hearing Officer, Illinois Pollution Control Board  
100 West Randolph Street, Suite 11-500  
Chicago, Illinois 60601  
(312) 814-6929 crowlek@ipcb.state.il.us