ILLINOIS POLLUTION CONTROL BOARD
February 4, 1988

IN THE MATTER OF:	)	
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AMENDMENTS TO 35 ILL. ADM. CODE 211 & 215 ORGANIC MATERIAL EMISSION STANDARDS AND LIMITATIONS FOR SYNTHESIZED PHARMACEUTICAL MANUFACTURING PLANTS.	)	R86-10

PROPOSED RULE. SECOND NOTICE.

OPINION AND ORDER OF THE BOARD (by J.D. Dumelle):

This matter comes before the Board upon a February 26, 1986, proposal for the adoption of amendments to 35 Ill. Adm. Code 211 and 215 filed by the Illinois Environmental Protection Agency (Agency). The proposal was accepted and authorized for hearing by Order of February 26, 1986. On April 23, 1987, the Agency submitted an amended proposal. Hearing was held on June 9, 1987, in Waukegan. The Agency filed a second amended proposal on July 27, 1987, and a third amended proposal on August 24, 1987. The second hearing was held on August 25, 1987 in Chicago. On September 21, 1987, the Agency filed the fourth amended proposal, which was presented at the third hearing, held September 22, 1987. On October 28, 1987, the Agency filed the fifth amended proposal, which was presented at the fourth hearing held October 30, 1987.

On August 6, 1987, the Board adopted an Order sending the Agency's second amended proposal to first notice publication in the Illinois Register. As a result of impending deadlines imposed by the Clean Air Act (42 U.S.C. 7401), the Board took no position on the merits of the Agency proposal at that time, but rather directed the proposal to first notice publication in an attempt to expedite the process of promulgating final regulations and to comply with the federal deadlines. First notice was published at 11 Ill. Reg. 14592 (Part 211) and 14617 (Part 215) on September 4, 1987. On September 24, 1987, the Secretary of State's Administrative Code Division filed comments on the proposal. Those changes have been adopted at second notice. Other comments have been filed by the Agency, Abbott Laboratories (Abbott), the North Shore Sanitary District (NSSD), and the United States Environmental Protection Agency[1] (USEPA).

[1] The Board notes that USEPA's comments were filed on December 14, 1987, after the scheduled comment period had expired. The comments were admitted into the record pursuant to Hearing (continued)

On November 13, 1987, the Department of Energy and Natural Resources (DENR) filed a negative declaration stating its determination that the preparation of a formal economic impact study is not necessary in this proceeding. The negative declaration was based on DENR's finding that "the cost of making a formal study is economically unreasonable in relation to the value of the study to the Board in determining the adverse economic impact of the regulation." Also filed on November 13, 1987 was notification of the concurrence of the Economic and Technical Advisory Committee (ETAC) in DENR's negative declaration.

Background

The overriding basis of the Agency's proposal is to correct deficiencies in the Illinois State Implementation Plan (SIP) which have been identified by the United States Environmental Protection Agency (USEPA). Section 172 of the Clean Air Act requires the state to impose the use of reasonably available control technology (RACT) on existing sources in non-attainment areas. On May 19, 1978, USEPA gave notice that the SIP must include, at least for major urban areas, enforceable regulations reflecting the application of RACT to those stationary sources for which USEPA has published control techniques guidelines (CTGs) since 1978. In December, 1978, a CTG was published entitled "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products."

On April 3, 1980, the Agency proposed in R80-5 regulations for the control of volatile organic materials from the manufacture of synthesized pharmaceuticals, together with other regulations generally known as the RACT II categories. On December 30, 1982, the Board adopted the proposed rules, but without provisions for the control of emissions from the manufacture of synthetic pharmaceuticals. On July 11, 1985, USEPA proposed, in part, to disapprove Illinois' Part D stationary source control strategy for failure to meet the RACT II control requirements, stating its belief that Illinois:

> "failed to adequately justify exempting this source category from the requirement of RACT. Further, the State's failure to adopt regulations covering the synthetic pharmaceutical manufacturing industry, leaves these sources totally unregulated. USEPA believes that cost can be considered in determining whether or not a regulation should be adopted. The State must, however, better

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Officer Order granting the Agency's Motion for Leave to File Instanter also filed December 14, 1987.

> support its decision not to adopt these regulations due to the unreasonably high costs. For example, Illinois could compare the control costs for this industry in other States to costs for this industry in Illinois. USEPA's analyses indicate that RACT exists for the synthetic pharmaceutical manufacturing industry."
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> (50 Fed. Reg. 28224-28226, July 11, 1985)

To remedy the deficiencies noted in USEPA's proposed disapproval, the Agency filed its proposal, initiating this proceeding, on February 26, 1986. the Board notes that this rulemaking proceeding has been highly contested since the outset, due in part to the fact that the proposed rules apply to only one business entity -- Abbott Laboratories.[2] Abbott has opposed the Agency's proposal throughout, and has submitted a proposal of its own, which is addressed below. As a result, gathering information sufficient to enable the Board to make a reasoned decision consistent with USEPA's proposed disapproval has proven a difficult task. However, after four hearings and five amendments refining the proposal to the complexities of Abbott's operations, the Board believes that there is sufficient evidence to support the Agency's position that its most recent proposal constitutes RACT for Abbott.

As previously stated, the Board ordered the Agency's second amended proposal to first notice. The final version of the Agency's proposal is comprised of the fifth amended proposal with minor amendments suggested by the Agency in its final comments of December 7, 1987. The Board notes that this final proposal could be sent to second first notice for publication. However, the Board does not believe that the public interest would be best served in this manner. First, the first notice published in August, 1987, gave ample notice of the proposal of regulations for pharmaceutical manufacturers. The subsequent Agency proposals constituted mere refinements to the proposal so as to better conform to Abbott's actual operations. Second, as will be

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[2] Abbott's manufacturing operations include two plants located approximately five miles apart in Lake County, Illinois. The North Chicago facility is a large complex devoted to fermentation facilities, synthetic pharmaceutical production, laboratory and pilot plant research and development, and administrative offices. The Abbott Park facility, located in an unincorporated area of Lake County, houses administrative offices, laboratory research and development, diagnostic kit assembly and pharmaceutical product preparation from bulk products manufactured at North Chicago or elsewhere.

discussed below, Abbott is the only source affected by the proposed rules, and it has actively participated throughout the proceeding. Thus, Abbott has had actual notice of each change in the proposal.

Applicability

At hearing, the Agency presented data that included the list of pharmaceutical manufacturers (Ex. 10, Table 3)[3] that would be potentially affected by the Agency's proposal. Proposed Section 215.480 would render the regulations applicable to sources emitting more than 6.8 kilograms per day (kg/day) (15 lbs/day) of volatile organic material and more than 2268 kg/year (2.5 tons/year), or, if less than 2.5 tons/year, to any single source exceeding 45.4 kg/day (100 lbs/day). Applying the 15 lbs/day, 2.5 ton/year standard to the list of manufacturers potentially affected, the Agency concluded that only Abbott's facilities would be affected by the proposed rule (R. 86). Although the fifth amended proposal amends the applicability criteria in certain respects, the Agency has not indicated that other facilities are thereby brought within the purview of the regulation. The Board believes that the regulations remain applicable only to Abbott.

Fifth Amended Proposal

From the outset, the Agency and Abbott have held and expressed widely divergent estimates of not only the actual, installed costs of control equipment but also, and more fundamentally, the maximum reasonable cost per ton of volatile organic material controlled. The CTG notes the complexities associated with the regulation of pharmaceutical manufacture:

> "Each plant is unique, differing from other plants in size, types of products manufactured, amounts and types of VOC used, and air pollution control problems encountered. The dissimilarities make it impossible to define typical emission levels or emission factors for an average plant. This in turn prevents identifying in this document which sources definitely need to be

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[3] Citations to the record in this action are made as follows: 1) references to the Board hearing transcripts are to "R. _____"; 2) references to exhibits received by the Board are to Ex. _____"; 3) references to public comments are to "P.C. _____".

> controlled and how much overall emission reduction can be effected."
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> (Ex. 6, p. 2-2).

Furthermore,

> "Because the amount and type of emissions vary widely from plant to plant, each control application will be unique. Therefore, in some situations control system construction materials, operating conditions, installation expenses, etc. will be different form those assumed in calculating costs for this chapter. In instances where regulatory decisions hinge on the cost of control, it would be proper to consider additional information that may more accurately reflect control costs for the plant in question."
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> (Ex. 6, p. 5-1).

The Agency secured the assistance of Mr. Thomas Ponder[4] in the development of the proposed regulations. Mr. Ponder prepared a report (Ex. 24) that was aimed at determining RACT for the Abbott facilities and testified (Ex. 23) that of the over 100 sources of volatile organic material (VOM) emissions at Abbott's facilities, only 12 sources (two in the fermentation facility at North Chicago and ten at the packaging facility at Abbott Park) were cost-effective to control. His report evaluated incinerators (both thermal and catalytic), condensation, refrigerated condensors, scrubbers and carbon absorbers and concluded that the 12 sources, emitting either acetone or ethanol, would have the most cost-effective controls if they employed scrubbers.

The control cost of other sources in Abbott's facilities (Buildings 200 and 800) which emitted less than 2.5 T/yr were also evaluated in the PEI report. However, Mr. Ponder recommended that such sources were infeasible to control since the cost effectiveness exceeds $5,000 per ton of VOM controlled. This approach is consistent with the control technique guideline (CTG) document (Ex. 6) which states that the

> "decision to require control of specific exhaust streams will be determined based on

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[4] Mr. Ponder, employed by USEPA as a consultant, is Vice President and Western Regional Manager of PEI Associates, Inc. (PEI). He is a certified cost engineer and has experience in volatile organic material control and cost effectiveness.

> local air quality, the mass emission rate of volatile organics, and the cost to the operator to control the streams."

The CTG does state that cost-effectiveness was not measured for this industry because annual emissions cannot be estimated in a manner "consistent with the costing techniques." This is due to the large variations in emissions from pharmaceutical manufacturing plants.

At the September 22, 1987 hearing, Abbott presented testimony that the cost-effectiveness of control was much greater than $5,000 per ton of VOM controlled. Abbott hired ETA, Inc. (ETA) to evaluate the implications of the Agency's proposed regulations. The ETA report (Ex. 39) lists the total annual emissions from Abbott's two plants at 131.4 T/yr with only 71.02 T/yr being affected by the proposed rule. This report identified 19 sources, 7 more than the PEI report. This comparison, presented in Table 2.3, Ex. 39, shows that different emissions were used for the individual sources. A more significant difference between the reports is that the ETA report only evaluated carbon adsorption and incineration for all sources at Abbott Park. For the emissions at the North Chicago Plant, incinerators and refrigerated condensors were considered, except for one source (PC 815) for which a scrubber was evaluated. The PEI report rules out incineration, carbon adsorption, and refrigerated condensors as being too expensive compared to scrubbers and identified packed bed scrubbers as the control method to be used at Abbott's facilities. Abbott has said that scrubbers cannot be used at Abbott Park because process water is not readily available and because of limitations of the municipal wastewater treatment system (R. 547-548; 454-455; 486-489). The ETA report presented the cost-effectiveness for control of the 19 sources, identified by them, which ranges from $3,723/ton (for a scrubber on the PC 815 source) to $37,177/ton (for a refrigerated condensor on the PC 802 source). The rest of the sources, except the two tray dryers, are fitted with incinerators.

The discrepancies in the two reports are (1) generally higher emissions from the sources as given to PEI by Abbott than the emissions used by Abbott (i.e., ETA), (2) use of different types of controls and failure of ETA to evaluate scrubbers, and (3) failure of PEI to take into account the correct costs of water and wastewater treatment.

The emissions discrepancy was explained at the September 22, 1987 hearing (R. 582-608). PEI was given the 1986 production forecast while ETA was provided the 1987 production forecast. Because of the wide variations in VOM emissions from day to day, cost-effectiveness numbers can change dramatically. Abbott has not provided the Board with the necessary historical data or the range of emissions that might be expected.

Abbott has not provided cost data on installation of scrubbers, which makes it very difficult to compare with the costs of control submitted by PEI. Abbott has summarily ruled out scrubbers except for one source (PC 815). Mr. Robertson, of Abbott Laboratories, provided operating and maintenance unit costs at Abbott (R. 488-489) from which the water and wastewater treatment costs are given below:

Item	Cost for North Chicago	Cost For Abbott Park
Lake Water	$0.142/1000 gal	
City Water	$1.00 /1000 gal	$1.05/1000 gal
Well Water		$0.40/1000 gal
Wastewater Treatment		
a) Abbott plant		
1. Flow	$0.30/1000 gal	
2. BOD	$0.350/lb	
b) Gurnee POTW		
1. Flow	$0.30/1000 gal	
2. BOD	$0.31/ lb	
3. TSS	$0.28/ lb	
c) Clavey Road POTW		
1. Flow		$0.30/1000 gal
2. BOD		$0.31/ lb
3. TSS		$0.29/ lb

Based on interviews on August 26, 1987 and October 12, 1987 conducted by Mr. Ponder, of PEI, with Ms. Penny Bouchard, of the North Shore Sanitary District (NSSD), Mr. Ponder stated that the wastewater treatment rates are $0.34 per thousand gallons of flow; $0.34/lb of BOD; and $0.31/lb of suspended solids, which would be applicable to Abbott discharged wastewater released to either the Gurnee or Waukegan plants which are closest to Abbott Laboratories (see Attachment 3, Ex. 59). At the final hearing on October 30, 1987, Mr. Ponder used the new emissions data that Abbott provided during the September 22, 1987 hearing and the NSSD wastewater treatment costs to come up with up-dated costs of control at Abbott's facilities (Ex. 59). The testimony of Mr. Ponder addressed the cost of acquiring well water where city water is not available. The recalculated cost estimates for emission control on 13 sources at the two Abbott facilities is found in Exhibit 59, Attachment 1, Table 1.

The change in the number of sources to be controlled is the result of the latest (1987 projection) emissions estimates provided by Abbott and the estimates of water and wastewater treatment costs. The control method with the lowest cost per ton of VOM controlled is also shown on the table in the above referenced Exhibit 59. Using a criterion of $5,000 per ton, the only sources Mr. Ponder recommended for control at Abbott's facilities which are cost-effective (C.E.) are:

a) one (1) source, PC 842 at N. Chicago - C.E. $2,060/ton with incinerator

b) two (2) tray driers at N. Chicago - Unit C.E. $2,226/ton with wet scrubber

c) eight (8) tunnel driers at Abbott Park - C.E. $4,450 with wet scrubber

d) two (2) accelacotas at Abbott Park - C.E. $4,250/ton with wet scrubber.

With regard to the water supply inadequacy problems cited by Abbott, Mr. Ponder states in Ex. 59 the following:

> "Information supplied by Abbott indicates that current water supply from the Niagara formation (sic) is inadequate, and there is currently not enough city water to supply these scrubbers [to control the tunnel driers and accelacotas at Abbott Park]. However the Well Company report clearly states that we could get more water by digging a deeper well. We evaluated the cost of that well and believe we could supply water for the scrubbers at 90 cents per gallon[5] based on new wells going over 1,000 feet deep. New water supplies, therefore, are not a problem at Abbott."

Abbott believes that PEI's estimated well cost of $130,000, resulting in $0.90 per 1000 gallons is unrealistically low and attempts to establish in Fig. 2.2, P.C. 3 that the well cost is $2.38/1000 gallons. The Board believes that Abbott's calculation of this figure is erroneous since it divides the total annual cost of four operating wells by the volume of water (in 1000 gallons) derived from only one well.

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[5] The Board believes that Mr. Ponder meant "90 cents per 1000 gallons."

Penny Bouchard, NSSD, submitted comments regarding the actual costs of discharging to NSSD's plants (P.C. 5). Ms. Bouchard states that various ordinances of the NSSD require that total costs are related to the specific user and must include (1) Permit fees, (2) Monitoring Costs, (3) User Charge fees and (4) Capital costs. PEI's estimate only included the User Charge fees, and even this figure may have been underestimated, according to Ms. Bouchard, since billing is based on the COD:BOD ratio of the wastewater. Abbott's wastewater has typically had a high COD:BOD ratio and has been charged more that $0.34/lb BOD, the number that is used by PEI in its calculations.

This information regarding the considerable costs of wastewater discharges from an industrial source, such as Abbott, to NSSD plants was also transmitted to J.E. Spessard, PEI, Inc. who in a November 20, 1987 memorandum, a copy of which was sent to Mr. Ponder, stated the following:

> "I have recalculated emission control costs for Abbott's two Accelacotas and eight tunnel driers .... Revised annual control costs are $40,750 for the Accelacotas ($6,400 per ton of VOC controlled) and $27,250 for the tunnel driers ($7,600 per ton ton of VOC controlled)."

Spessard's memorandum was attached to a cover letter from Mr. Ponder, PEI, to the Agency which states that the cost of controlling the emissions of VOM from the Accelacotas and the tunnel driers would exceed $5,000/ton. (Attachment 4, P.C. 4). Based on this new information, the Agency submitted comments on December 7, 1987 (P.C. 4) which request the Board to amend the Agency's fifth amended proposal which would require Abbott to control a total of only three (3) sources, namely, PC 842 and two tray driers, located at the North Chicago plant. The Board accepts the Agency's amendments: the second notice Order includes the suggested revisions.

Final Agency Proposal

As the final version of the proposed regulations control only the three above-named sources, this Opinion will focus its evaluation of costs on only those three sources. The costs of controlling these three sources will be evaluated by comparing the cost of control as estimated by PEI for the Agency and ETA for Abbott. The comparison is illustrated by the following table:

	VOM (T/yr)		Cost ($)					
Source	Emitted		Controlled	Total Capital	Annual	Calculated per ton	by	Comments
PC 842	2.09#	1.88	10,800*	3,864	2,060	PEI	Incinerator	
	2.09#	1.88	51,300*	15,871	8,442	ETA	Incinerator	
Tray Driers:								
No. 1	3.38	3.04	7,000	6,903	2,297	PEI	Scrubber	
No. 2	3.38	3.04	7,000	6,903	2,297	PEI	Scrubber	
Nos. 1&2	7.76	6.08	7,000	12,010	1,975	PEI	One scrubber for both driers	
No. 1	3.38	3.04	25,600	12,143	3,992	ETA	Scrubber	
No. 2	3.38	3.04	25,600	12,143	3,992	ETA	Scrubber	

#Emissions are less than 2.5 T/yr, but exceed 100 lb/day
*Costs are based on a flow rate of 700 acfm

PC 842

For reactor PC 842, Mr. Ponder recommended and the Agency proposed control using a small incinerator. PEI estimated an installed capital cost of $10,800. Abbott estimated an installed capital cost of $51,300. The Agency contends that ETA's estimated costs for the incinerator to control emissions from PC 842 are "outdated and do not reflect true market conditions. "ETA's estimates are based on ten-year old costs data for large, custom-designed incinerators. "Presently, many companies offer smaller, factory-assembled incinerators at much lower prices." (P.C. 4). The Agency bases its statement on a review of ETA's cost estimating methodology for thermal incineration by Spessard of PEI (Attachment 2, P.C. 4), which gives convincing arguments for accepting PEI's cost estimates as being more realistic based on equipment and availability. ETA also presented some vendor quotes, the lowest incinerator being $19,000 for a flow of 100 acfm (received by the Board November 13, 1987). Mr. Ponder, PEI, stated in testimony that "[W]e had different vendor quotes than they [ETA] have. I am not sure exactly why... They didn't use the same vendors." (R. 902). PEI also submitted a revised vendor survey (received by the Board November 30, 1987). In PEI's survey, vendors were asked for the cost of an incinerator at a flow rate of 300 cfm. The lowest cost was from the National Incinerator Company for $5,000.

Based on all the information provided, the Board finds that the costs of installation used by ETA appear rather high. However, the unit cost of the incinerator used by PEI might be

low since they extrapolated from costs obtained for a 300 acfm incinerator to one operating at a 700 acfm flow rate. Because packaged, skid-mounted incineration units are available, the actual costs are unlikely to be as high as projected by ETA. The cost per ton is also a function of the actual amounts of VOM controlled. Since these emissions are small and only one incinerator is involved, the Board finds that the cost predicted to be incurred by Abbott in installing an incinerator to control PC 842 will not be unreasonably high.

Tray Driers

Mr. Ponder also recommended control by wet scrubber on two tray driers at the North Chicago facility. The Agency states that although Mr. Ponder believes that one scrubber could serve both tray driers (at a cost of $1,975 per ton), he evaluated the installation costs of separate scrubbers for the two driers (P.C. 4, p. 6). The total capital cost of a scrubber for each tray drier is $7,000, which results in a cost of $2,297, per ton of VOM controlled, well under $3,000 per ton (P.C. 4, p. 6). Abbott, however, estimated that the total capital cost of a scrubber for each tray drier is $25,600, which translates into a cost of $3,992 per ton of VOM controlled. Based on the information in the record, the Board believes that Abbott's estimates are high for the fairly small scrubber required. The Board believes that emissions from the tray driers can be controlled at a cost of less than $3,000 per ton which, without implying that $3,000 is necessarily the cut-off for RACT, the Board believes is reasonable.

Abbott estimated the total VOM emissions from its pharmaceutical operations, in the absence of control, at 4,627.3 T/yr and claimed that it is controlling 97.2% with existing controls (Ex. 52). These existing controls at Abbott's plants are process-related or required because of Occupational Safety and Health Administration regulations (R. 685). Abbott is able to achieve a higher level of control because it uses cooler (Lake Michigan) condenser water which results in lower VOM emissions. The Board notes that the Agency's final proposal adopted at second notice is still based on the CTG for this category with some modifications that take into account Abbott's operation. Thus the rule as adopted is expected to result in less than 8 T/yr of VOM reductions. However, this reduction is in addition to the 97.2% (i.e. 4497.7 T/yr) VOM reduction already achieved with existing (CTG recommended) controls. Thus all of Abbott's controllable sources are brought under this proposed rule for controlling synthesized pharmaceutical manufacturing plant VOM emissions. This fulfills the state's requirement, under Section 172 of the Clean Air Act, to adopt enforceable RACT regulations.

Abbott Laboratories Proposal

At hearing on October 30, 1987, Abbott submitted an alternative proposal for the pharmaceutical industry. Abbott states that its proposal "embodies Abbott's existing level of control and would require certain controls on CTG and non-CTG sources based on a cost effectiveness of $3,000 per ton." Abbott believes that its proposal is approvable because it is "based on a reasonable cost effectiveness value."

The Agency objects to Abbott's proposal. The Agency believes that Sections 215.480, 215.481, 215.482, and 215.486 contain emission level cut-offs that are not justifiable as RACT and, therefore, not approvable by USEPA. Further, the Agency states that in Section 215.480 and 215.486 of Abbott's proposal laboratory hoods have been deleted as a source category, and in Section 215.481 centrifuges have been totally exempted by exclusion. The Agency's position on such emissions is that,

> "Although no lab hoods or centrifuges at Abbott's facilities presently meet the 2.5 ton per year threshold, the Agency believes these sources would become cost effective to control should emissions increase beyond 2.5 tpy (R. pp. 207-208). Lab hoods and centrifuges are thus best treated as the Agency is treating all other sources: by designating an exemption emission level beyond which the source becomes cost effective to control." (P.C. 4, p. 8).

The Agency also objects to Section 215.487 of Abbott's proposal, which would allow Abbott the option of using the calculation procedures of the CTG as a substitute for being required to conduct a stack test pursuant to 40 CFR 60, Appendix A, Methods 25, 25A or 25B. The Agency states:

> [i]n regulating this category of emission sources the Agency will not likely routinely request stack tests to determine compliance, however, if changed circumstances or new, future information indicate a need to test for compliance, the Agency reserves the right to request a test from the methods listed. Some compliance questions cannot be satisfied simply and exclusively on the basis of calculations." (P.C. 4, pp. 8-9).

In response to a request by the Agency, USEPA conducted a review of Abbott's proposal and submitted its comments to the Board on December 14, 1987. USEPA's overall position on Abbott's proposal is that "if formally submitted to USEPA, it would be

proposed for disapproval in the Federal Register" (P.C. 7, p. 3). On the stack test requirement of Section 215.487, USEPA states:

> The Section is not approvable because it precludes [the State of] Illinois' ability to require a stack test. This capability is necessary because it may not always be possible to accurately calculate a source's emission rate. Stack test results must clearly supercede (sic) the results obtained by calculations which are not based upon USEPA approved stack test methods." (P.C. 7, p. 3).

In response to Abbott's proposed Section 215.480, USEPA states that averaging emissions from batch operations over the duration of the batch operation could present a serious rule enforceability problem.

> "For existing source, averaging any volatile organic compound (VOC) emissions over a period in excess of 24 hours can only be done in accordance with the January 20, 1984, memorandum from John O'Connor, former Acting Director of the Office of Air Quality Planning and Standards, and only as source specific State Implementation Plan (SIP) revisions. This memorandum, entitled "Averaging Times for Compliance with VOC Emission Limits - SIP Revision Policy," prohibits greater than 24-hour averaging (which could occur from a batch operation) by VOC sources in the Chicago area because of its lack of an approved ozone SIP." (P.C. 7, p. 1).

USEPA stated, in addition, that an adequate basis for deleting laboratory hoods from the list of applicable sources had not been established.

USEPA also commented on Abbott's proposed exemption levels. USEPA stated that the exemptions levels, "which are substantially in excess of Abbott's emission levels, are not approvable." (P.C. 7, p. 2).

> USEPA's guidance for synthesized pharmaceutical plants specifies applicability criteria of 15 lb/day for all sources of VOC. The only area in which Abbott has demonstrated that its synthesized pharmaceutical operations differ from those in the Control Technique Guideline (CTG) is in its use of Lake Michigan water. However,

> Illinois' proposal takes into consideration this additional cooling (which results in reduced emissions) by adding an annual exemption level. This annual exemption level has the effect of eliminating sources which can on occasion exceed 15 lbs/day, from the specified control requirements." (P.C. 7, p. 2).

Finally, USEPA noted that Abbott's proposal included a number of exemption levels which are higher than current emissions. USEPA stated:

> "[t]hese exemption levels are apparently based upon the highest emission levels which can occur before the dollars per ton of control go below $3,000/ton (according to Abbott). Abbott considers $3,000/ton as the highest cost-effectiveness value which is consistent with RACT ... [T]here is no basis for Abbott's use of $3,000/ton as a yardstick for establishing RACT." (P.C. 7, p. 2).

On January 8, 1988, Abbott filed its Response to USEPA Comments with a Motion for Leave to File Instanter, which was granted by Hearing Officer Order on January 18, 1988. Abbott devoted several pages of comment to "the manner in which USEPA has elected to participate in this proceeding" and tendered responses to USEPA's comments. The Board is not persuaded by this Response that the record contains information and evidence sufficient to overcome the indication, by USEPA itself, that the proposal of Abbott is not approvable. The Board's charge is to promulgate approvable regulations imposing RACT on sources in non-attainment areas. The Board is persuaded that the Agency's proposal satisfies that charge, and the Board believes that the Agency's version is approvable by USEPA. Therefore, the Board declines to implement the language proposed by Abbott.

Section 215.102 Measurement of Vapor Pressures

The Agency proposed to amend Section 215.102, Testing Methods, to add a subsection on the measurement of vapor pressures. The Agency proposed similar language in R86-37, a proceeding devoted to the definition of Volatile Organic Material. However, in R86-37, which was adopted for final notice on December 22, 1987, and published at 12 Ill Reg. 815, January 8, 1988, the Board adopted certain amendments to the Agency's proposed language. First, for a single component, the vapor pressure is to be determined by ASTM (American Society of Testing and Materials) Method D-2879-83, or may be obtained from a published source, such as the sources listed in Section 215.102(b)(1). The revision was necessitated in R86-37 by JCAR

(Joint Committee on Administrative Rules) comment that, in its view, the language as proposed by the Agency constituted an improper series of incorporations by reference. Specifically, JCAR believed that the textbooks listed were improper sources for incorporation into the Administrative Code, as the Administrative Procedures Act makes no provision for the incorporation of textbooks. As a result, the language was revised to avoid the characterization of the textbooks as incorporations by reference. The Board notes that the language proposed in R86-37 has been finalized. Thus, much of the language proposed at first notice in this proceeding is no longer necessary: it has already been adopted.

However, the Board has made certain changes to Section 215.102(b)(2), regarding determination of the vapor pressure of a mixture. At the final hearing, Dr. Harish Rao, of the Board's Scientific and Technical Staff, noted that there was concern expressed during the course of the hearings that the Agency's proposed language was not clear. Dr. Rao offered alternate language, aimed at clarifying the Agency's intent, and requested comment from the participants. Both the Agency (P.C. 1) and Abbott (P.C. 2) agreed that Dr. Rao's language is an acceptable substitute for the Agency's language and intent. However, Abbott objected to the application of Section 215.102(b)(2), stating:

> "the true vapor pressure of a mixture is equal to the sum of the actual vapor pressures of each component of the mixture (whether or not the mixture is a VOM as defined by regulation) weighted by its mole fraction in the mixture... any other method of calculation which does not take into account every component, will not yield the correct vapor pressure of a mixture." (P.C. 2, pp. 1-2).

Abbott also criticizes the Agency's proposed method as being "inconsistent with the methodologies embodied in the CTG for other RACT categories upon which the Board has based its other corresponding RACT regulations." To alleviate the concerns expressed public comment, the Board has added language to permit the determination of the actual vapor pressure of a mixture pursuant to ASTM Method D-2879-83, since the Agency's proposed language may not yield the correct vapor pressure of the mixture. However the Board assumes that the Agency's proposed measurement procedure will provide a more conservative approach to the control of VOM emissions from pharmaceutical plant operations. Because the Agency's proposed language states that the vapor pressure of a mixture "may be taken as either" rather than "is either" in Section 215.102(b)(2), the Board has opted to retain the Agency's proposed method to provide an alternative to the ASTM method.

Finally, the Board notes that the language "organic material or volatile organic material" has been changed to "volatile organic liquid" and that "not" has been deleted in Section 215.102(b)(2)(A). Also, in 215.102(b)(2), language was added clarifying the sections applicability only to Subpart T.

Definition of VOM

In the first notice proposal, amendment was proposed to the definition of volatile organic material (VOM). As has been previously noted, R86-37 was a proceeding devoted entirely to the definition of VOM. The Agency has indicated in other rulemaking proceedings (i.e., R86-40) that it included the proposed amendment to VOM in proceedings other than R86-37 simply to put the regulated community on notice that the definition was in the process of change. As R86-37 has been adopted and is in effect, the Board deems it appropriate to remove the definition of VOM from further consideration in this proceeding.

Compliance Date

In its final comments, the Agency suggested amendment to the proposal to provide a compliance date of April 1, 1989. The Agency noted that:

> [t]he adoption of the Agency Proposal would require Abbott to install a small incinerator and two wet scrubbers at its North Chicago Plant. Mr. Ponder and Dr. Reed, both of whom have extensive experience in VOM control methods, have concluded that a period of one year from the effective date of the proposed rule constitutes an ample time period for compliance in this case. (P.C. 4, p. 3).

Further, the Agency stated that "USEPA's interpretation of the Clean Air Act and regulations [thereunder] do not mandate a December 31, 1987 compliance date. To support this position, the Agency points to a number of indications, including (1) Proposed USEPA Approval of Kansas Ozone SIP, (52 FR 36963-36967), which includes compliance dates beyond December 31, 1987, (2) Summary of EPA's Proposed Ozone and Carbon Monoxide Attainment Policy dated November 10, 1987, which defines "near term attainment" of the ozone standard as being three to five years from the date of SIP approval, and (3) SIP: Approval of Post-1987 Ozone and Carbon Monoxide Plan Revisions for Areas Not Attaining the NAAQS, (52 FR 45044-45121), which states that the meaning of "near term" is within three years and, for some areas, five years of EPA's approval of the Area's post-1987 plan revision. (P.C. 4, pp. 3-4).

Abbott does not disagree with the concept of proposing a compliance date after December 31, 1987. However, Abbott objected to the criteria used to arrive at the April 1, 1989 compliance date, and proposed a December 31, 1989 as being preferable "due to the uncertainties inherent in the permit process." (P.C. 8, p. 6). Abbott's objection to the April 1, 1989 compliance date stems from the Agency's conclusion that "a period of one year from the effective date of this proposed rule constitutes an ample time period for compliance in this case" (See P.C. 8, p. 4). Abbott notes that the Agency's conclusion is based on statements by Mr. Ponder of PEI and Dr. Reed of the Agency. Abbott argues that Mr. Ponder is:

> "not qualified to render an opinion concerning the length of time required by IEPA to permit any particular source or item of control equipment. The permit process cannot be conducted entirely concurrent with the design, procurement, construction and installation of new control equipment. The permit issues must be substantially resolved before Abbott or any other source could reasonably be expected to purchase the required equipment or begin construction and installation. Even the final design of the equipment could be affected by potential permit conditions, of which Abbott would need to be certain before the equipment could be selected and purchased. IEPA often requests additional information during the permit application review period, and it is often necessary to waive the permit decision deadline to allow IEPA to complete its review process, determine the particular permit conditions and issue the final permit." (P.C. 8, p. 5).

Abbott also argues that "the record does not show that Dr. Reed has extensive experience in VOM control methods:

> His conclusion that Abbott could come into compliance with the proposed regulation in one year is speculative and is supported only by telephone calls to two vendors. Abbott did not testify that it would purchase any required control equipment from these vendors. Abbott does not know if the control equipment manufactured by these two vendors is suitable, either in performance or materials of construction, for the intended applications." (P.C. 8, p. 5).

The Board, perhaps better than anyone, realizes the injustice that would result from a December 31, 1987 deadline imposed in this rule, as that date has already passed. The Board notes that it has considered this issue in other RACT proceedings. However, information justifying a date later than December 31, 1987 had not been submitted into the records of those proceedings, and the Board had been bound by the evidence in the record. Here, the Board is pursuaded that the record justifies a date later than December 31, 1987. The only issue remaining is which date to impose. The Board is not persuaded by Abbott's evaluations of the credentials of Mr. Ponder and Dr. Reed. Thus, the Board is not persuaded that Abbott's criticisms of the April 1, 1989 deadline are based on solid foundation. Rather, the Board agrees that a time period of approximately one year from the date of adoption of the rules will provide Abbott ample time in which to comply with the regulations. Therefore, the Agency's suggested compliance date of April 1, 1989 is accepted and incorporated at second notice.

Incorporation by Reference

Certain materials have been incorporated by reference into Section 215.105, Incorporations by Reference. First, proposed Section 215.487 states that certain test procedures are to be consistent with USEPA document EPA-450/2-78-041. The Board notes that because this material constitutes a standard or guideline of an agency of the United States, the material must be incorporated pursuant to Section 6.02(b) of the Administrative Procedure Act, which requires prior approval by JCAR. The Board applied for and on December 21, 1987 received written approval by JCAR to incorporate the material by reference.

Second, ASTM D 1946-67 and ASTM D 2382-76 [American Society for Testing and Materials] test methods have been added to the list of incorporations by reference. In R86-39, Synthetic Organic Chemical and Polymer Manufacturing, and R86-40, Air Oxidation Processes in the Synthetic Organic Chemical Manufacturing Industry, the Board adopted regulations which utilize these two ASTM procedures. During the second notice phase of those two rulemakings, JCAR objected to the inclusion of the two ASTM references in Section 215.105 because, according to JCAR, a section may not be proposed for amendment at second notice that was not proposed for amendment at first notice. There, Section 215.105 had not been proposed for amendment at first notice. However, because Section 215.105 had been proposed for amendment in this proceeding, JCAR suggested that the Board incorporate the ASTM methods in this proceeding. The Board agreed and hereby complies with JCAR's suggestion. ASTM D 1946-67 and ASTM D 2382-76 have been added at second notice.

ORDER

The Board hereby directs the Clerk of the Board to submit the proposed amendments to 35 Ill. Adm. Code 211 and 215 to the Joint Commission on Administrative Rules for second notice review:

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE B: AIR POLLUTION
CHAPTER I: POLLUTION CONTROL BOARD
SUBCHAPTER c: EMISSION STANDARDS AND LIMITATIONS FOR STATIONARY SOURCES

PART 211
DEFINITIONS AND GENERAL PROVISIONS

SUBPART A: GENERAL PROVISIONS

Section
211.101 Incorporations by Reference
211.102 Abbreviations and Units

SUBPART B: DEFINITIONS

Section
211.121 Other Definitions
211.122 Definitions

Appendix A Rule into Section Table
Appendix B Section into Rule Table

AUTHORITY: Implementing Sections 9 and 10 and authorized by Section 27 of the Environmental Protection Act (Ill. Rev. Stat. 1985, ch. 111½, pars. 1009, 1010 and 1027).

SOURCE: Adopted as Chapter 2: Air Pollution, Rule 201: Definitions, R71-23, 4 PCB 191, filed and effective April 14, 1972; amended in R74-2 and R75-5, 32 PCB 295, at 3 Ill. Reg. 5, p. 777, effective February 3, 1979; amended in R78-3 and 4, 35 PCB 75 and 243, at 3 Ill. Reg. 30, p. 124, effective July 28, 1979; amended in R80-5, at 7 Ill. Reg. 1244, effective January 21, 1983; codified at 7 Ill. Reg. 13590; amended in R82-1 (Docket A) at 10 Ill. Reg. 12624, effective July 7, 1986; amended in R85-21(A) at 11 Ill. Reg. 11747, effective June 29, 1987; amended in R86-34 at 11 Ill. Reg. 12267, effective July 10, 1987; amended in R86-39 at 11 Ill. Reg. 20804, effective December 14, 1987; amended in R82-14 and R86-37 at 12 Ill. Reg. 787, effective December 24, 1987; amended in R86-10 at 12 Ill. Reg. ____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 211.122 Definitions

"In-Process Tank": A container used for mixing, blending, heating, reacting, holding, crystallizing, evaporating, or cleaning operations in the manufacture of pharmaceuticals.

"Pharmaceutical": Any compound or mixture, other than food, used in the prevention, diagnosis, alleviation, treatment or cure of disease in man and animal.

"Production Equipment Exhaust System": A system for collecting and directing into the atmosphere emissions of volatile organic material from reactors, centrifuges and other process emission sources.

"Reactor": A vat, vessel or other device in which chemical reactions take place.

"Surface Condenser": A device which removes a substance from a gas stream by reducing the temperature of the stream, without direct contact between the coolant and the stream.

(Source: Amended at ___ 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 215
ORGANIC MATERIAL EMISSION STANDARDS AND LIMITATIONS

SUBPART A: GENERAL PROVISIONS

Section
215.100 Introduction
215.101 Clean-up and Disposal Operations
215.102 Testing Methods
215.103 Abbreviations and Conversion Factors
215.104 Definitions
215.105 Incorporations by Reference
215.106 Afterburners
215.107 Determination of Applicability

SUBPART B: ORGANIC EMISSIONS FROM STORAGE AND LOADING OPERATIONS

SUBPART C: ORGANIC EMISSIONS FROM MISCELLANEOUS EQUIPMENT

SUBPART E: SOLVENT CLEANING

SUBPART F: COATING OPERATIONS

SUBPART H: SPECIAL LIMITATIONS FOR SOURCES IN MAJOR URBANIZED AREAS WHICH ARE NONATTAINMENT FOR OZONE

SUBPART K: USE OF ORGANIC MATERIAL

SUBPART N: VEGETABLE OIL PROCESSING

SUBPART P: PRINTING AND PUBLISHING

SUBPART Q: LEAKS FROM SYNTHETIC ORGANIC CHEMICAL AND POLYMER MANUFACTURING EQUIPMENT

SUBPART R: PETROLEUM REFINING AND RELATED INDUSTRIES; ASPHALT MATERIALS

SUBPART S: RUBBER AND MISCELLANEOUS PLASTIC PRODUCTS

SUBPART T: PHARMACEUTICAL MANUFACTURING

SUBPART U: COKE MANUFACTURING AND

BY-PRODUCT RECOVERY

SUBPART V: AIR OXIDATION PROCESSES

SUBPART W: AGRICULTURE

SUBPART X: CONSTRUCTION

SUBPART Y: GASOLINE DISTRIBUTION

SUBPART Z: DRY CLEANERS

SUBPART BB: POLYSTYRENE PLANTS

AUTHORITY: Implementing Section 10 and authorized by Section 27 of the Environmental Protection Act (Ill. Rev. Stat. 1985, ch. 111½ pars. 1010 and 1027).

SOURCE: Adopted as Chapter 2: Air Pollution, Rule 205: Organic Material Emission Standards and Limitations, R71-23, 4 PCB 191, filed and effective April 14, 1972; amended in R77-3, 33 PCB 357, at 3 Ill. Reg. 18, p. 41, effective May 3, 1979; amended in R78-3 and R78-4, 35 PCB 75, at 3 Ill. Reg. 30, p. 124, effective July 28, 1979; amended in R80-5 at 7 Ill. Reg. 1244, effective January 21, 1983; codified at 7 Ill. Reg. 13601; Notice of Corrections at 7 Ill. Reg. 14575; amended in R82-14 at 8 Ill. Reg. 13254, effective July 12, 1984; amended in R83-36 at 9 Ill. Reg. 9114, effective May 30, 1985; amended in R82-14 at 9 Ill. Reg. 13960, effective August 28, 1985; amended in R85-28 at 11 Ill. Reg. 3127, effective February 3, 1987; amended in R82-14 at 11 Ill. Reg. 7296, effective April 3, 1987; amended in R85-21(A) at 11 Ill. Reg. 11770, effective June 29, 1987; recodified in R86-39 at 11 Ill. Reg. 13541; amended in R82-14 and R86-12 at 11 Ill. Reg. 16706, effective September 30, 1987; amended in R85-21(B) at 11 Ill. Reg. 19117, effective November 9, 1987; amended in R86-36, R86-39, R86-40 at 11 Ill. Reg. 20829, effective December 14, 1987; amended in R82-14 and R86-37 at 12. Ill. Reg. 815, effective December 24, 1987; amended in R86-10 at 12 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 215.102 Testing Methods

a) The total organic material concentrations in an effluent stream shall be measured by a flame ionization detector, or by other methods approved by the Illinois Environmental Protection Agency (Agency), according to the provisions of 35 Ill. Adm. Code 201.

b) Measurement of Vapor Pressures

1) For a single-component, the actual vapor pressure shall be determined by ASTM (American Society of Testing and Materials) Method D-2879-83 (Approved 1983), incorporated by reference in Section 215.105, or the vapor pressure may be obtained from a published source such as: Boublik, T., V. Fried and E. Hala, "The Vapor Pressure of Pure Substances," Elsevier Scientific Publishing Co., New York (1973), Perry's Chemical Engineer's Handbook, McGraw-Hill Book Company (1984), CRC Handbook of Chemistry and Physics, Chemical Rubber Publishing Company (1986-87), Lange's Handbook of Chemistry, John A. Dean, editor, McGraw-Hill Book Company (1985).

2) For a mixture, the actual vapor pressure shall be determined by ASTM (American Society of Testing and Materials) Method D-~~2789~~2879-83 (Approved 1983), incorporated by reference in Section 215.105, or the vapor pressure may be taken as either:

A) If the vapor pressure of the ~~organic material or~~ volatile organic ~~material~~ liquid is ~~not~~ specified in the applicable rule, the lesser of the sum of the actual vapor pressure of each component or each volatile organic material component, as determined in accordance with 215.102(b)(1), weighted by its mole fraction; or

B) If the vapor pressure of the organic material or volatile organic material is specified in the applicable rule, the sum of the actual vapor pressure of each component as determined in accordance with 215.102(b)(1) weighted by its mole fraction.

Section 215.105 Incorporations by Reference

The following materials are incorporated by reference:

a) American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103:

1) ASTM D 1644-59 Method A

2) ASTM D 1475-60

3) ASTM D 2369-73

4) ASTM D 2879-83 (Approved 1983)

5) ASTM D 323-82 (Approved 1982)

6) ASTM D 86-82 (Approved 1982)

7) ASTM E 260-73 (Approved 1973), E 168-67 (Reapproved 1977), E 169-63 (Reapproved 1981), E 20 (Approved 1985)

8) ASTM D 97-66

9) ASTM D 1946-67

10) ASTM D 2382-76

b) Federal Standard 141a, Method 4082.1

c) National Fire Codes, National Fire Prevention Association, Battery March Park, Quincy, Massachusetts 02269 (1979)

d) United States Environmental Protection Agency, Washington, D.C., EPA-450/2-77-026, Appendix A.

e) United States Environmental Protection Agency, Washington, D.C., EPA-450/2-78-051 Appendix A and Appendix B (December 1978).

f) Standard Industrial Classification Manual, published by Executive Office of the President, Office of Management and Budget, Washington, D.C., 1972

g) 40 CFR 60, Appendix A, 1986

h) United States Environmental Protection Agency, Washington D.C., EPA-450/2-78-041.

(Board Note: The incorporations by reference listed above contain no later amendments or editions.)

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

SUBPART T: PHARMACEUTICAL MANUFACTURING

Section 215.480 Applicability of Subpart T

a) The rules of this Subpart, except for Sections 215.483 through 215.485, apply to all emission sources of volatile organic material, including but not limited to reactors, distillation units, dryers, storage tanks for volatile organic liquids, equipment for the transfer of volatile organic liquids, filters, crystallizers, washers, laboratory hoods, coating operations, mixing operations and centrifuges used in manufacturing, including packaging, of pharmaceuticals, and emitting more than 6.8 kg/day (15 lbs/day) of volatile organic material and more than 2268 kg/year (2.5 tons/year) of volatile organic material, or, if less than 2.5 tons/year, these sections still apply if emissions from any single source exceed 45.4 kg/day (100 lbs/day).

b) The following emissions shall be excluded from a determination of what constitutes more than 2268 kg/year (2.5 tons/year) of VOM for the purposes of subsection (a) above: not more than 4535 kg/year (5.0 tons/year) of volatile organic material from each fluid bed drier or each tunnel drier, and not more than 6803 kg/year (7.5 ton/year) of VOM from each Accelacota. This subsection shall apply only to fluid bed driers, tunnel driers and Accelacotas located in Libertyville Township, Lake County, Illinois, and only when such emissions are not vented to air pollution control equipment.

c) Sections 215.483 through 215.485 apply to a plant having one or more emission sources that:

1) are used to manufacture pharmaceuticals; and

2) emit more than 6.8 kg/day (15 lbs/day) of volatile organic material and more than 2268 kg/year (2.5 tons/year) of volatile organic material, or, if less than 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 person shall violate any condition in a permit when the condition results in exclusion of an emission source from this Part 215, Subpart T.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.481 Control of Reactors, Distillation Units, Crystallizers, Centrifuges and Vacuum Dryers

a) The owner or operator shall control all reactors, distillation units, crystallizers, centrifuges and vacuum dryers that are used to manufacture pharmaceuticals with surface condensers operated such that the condenser outlet gas temperature does not exceed:

1) 248.2 K (-13 F) when condensing volatile organic material of vapor pressure greater than 40.0 kPa (5.8 psi) at 294.3 K (70 F); or

2) 258.2 K (5 F) when condensing volatile organic material of vapor pressure greater than 20.0 kPa (2.9 psi) at 294.3 K (70 F); or

3) 273.2 K (32 F) when condensing volatile organic material of vapor pressure greater than 10.0 kPa (1.5 psi) at 294.3 K (70 F); or

4) 283.2 K (50 F) when condensing volatile organic material of vapor pressure greater than 7.0 kPa (1.0 psi) at 294.3 K (70); or

5) 298.2 K (77 F) when condensing volatile organic material of vapor pressure greater than 3.45 kPa (0.5 psi) at 294.3 K (70 F).

b) The owner or operator shall enclose all centrifuges used to manufacture pharmaceuticals and that have an exposed volatile organic liquid surface, where the volatile organic material in the volatile organic liquid has a vapor pressure of 3.45 kPa (0.5 psi) or more at 294.3 K (70 F).

c) The owner or operator shall enclose all centrifuges used to manufacture pharmaceuticals and that have an exposed volatile organic liquid surface, where the volatile organic material in the volatile organic liquid has a vapor pressure of 3.45 kPa (0.5 psi) or more at 924.3 K (70 F).

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.482 Control of Air Dryers, Production Equipment Exhaust Systems and Filters

a) The owner or operator of an air dryer or production equipment exhaust system used to manufacture pharma-

ceuticals shall control the emissions of volatile organic material from such emission sources by air pollution control equipment which reduces by 90 percent or more the volatile organic material that would otherwise be emitted into the atmosphere.

b) The owner or operator shall enclose all rotary vacuum filters and other filters used to manufacture pharmaceuticals and that have an exposed volatile organic liquid surface, where the volatile organic material in the volatile organic liquid has a vapor pressure of 3.45 kPa (0.5 psi) or more at 294.3 K (70 F).

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

Section 215.483 Material Storage and Transfer

The owner or operator of a pharmaceutical manufacturing plant shall:

a) Provide a vapor balance system or equivalent control system that is at least 90.0 percent effective in reducing volatile organic material emissions from truck or railcar deliveries to storage tanks with capacities equal to or greater than 7.57m^3 (2,000 gallons) that store volatile organic liquids with vapor pressures greater than 28.0 kPa (4.1 psi) at 294.3 K (70 F); and

b) Install pressure/vacuum conservation vents set at 0.2 kPa (0.03 psi) on all storage tanks that store volatile organic liquids with vapor pressures greater than 10 kPa (1.5 psi) at 294.3 K (70 F),unless a more effective control system is used.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.484 In-Process Tanks

The owner or operator shall install covers on all in-process tanks used to manufacture pharmaceuticals and containing a volatile organic liquid at any time. These covers must remain closed, except when production, sampling, maintenance, or inspection procedures require operator access.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.485 Leaks

The owner or operator of a pharmaceutical manufacturing plant shall repair any component from which a leak of volatile organic liquid can be observed. The repair shall be completed as soon as practicable but no later than 15 days after the leak is found unless the leaking component cannot be repaired until the process unit is shut down, and the leaking component must then be repaired before the unit is restarted.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.486 Other Emission Sources

The owner or operator of a washer, laboratory hood, capsule coating operation, mixing operation, or any other process emission source not subject to Section 215.481 through 215.485 of this Subpart, and used to manufacture pharmaceuticals shall control the emissions of volatile organic material from such emission sources by:

a) Air pollution control equipment which reduces by 81 percent or more the volatile organic material that would otherwise be emitted to the atmosphere, or

b) A surface condenser which captures all the volatile organic material which would otherwise be emitted to the atmosphere and which meets the requirements of Section 215.481(a) of this Subpart.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.487 Testing

a) The owner or operator of any volatile organic material emission source subject to this Subpart shall, at his own expense, demonstrate compliance by methods or procedures listed in Section 215.487(c).

b) All tests pursuant to Section 215.487(a) shall be performed in conformance with the procedures set forth in 35 Ill. Adm. Code 283.

c) Test procedures to determine operation and maintenance compliance with this Subpart shall be consistent with EPA-450/2-78-041, incorporated by reference in Section 215.105. Procedures for testing air pollution control equipment to determine compliance with this Subpart shall use Part 230, Appendix A Method 25 (40 CFR 60, Appendix A Method 25).

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.488 Monitors for Air Pollution Control Equipment

a) At a minimum, continuous monitors for the following parameters shall be installed on air pollution control equipment subject to this Subpart:

1) Destruction device combustion temperature;

2) Temperature rise across a catalytic afterburner bed;

3) Breakthrough of volatile organic material on a carbon adsorption unit.

b) Each monitor shall be equipped with a recording device.

c) Each monitor shall be calibrated quarterly.

d) Each monitor shall operate at all times while the associated control equipment is operating.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.489 Compliance Schedule

a) The owner or operator of an emission source subject to this Subpart, the construction or modification of which has commenced prior to (effective date of rule) must complete on-site construction or installation of the emission control or process equipment, or both, so as to operate in compliance with this Subpart by April 1, 1989.

b) The owner and operator of any emission source subject to this Subpart, the construction or modification of which has not commenced prior to (effective date of rule), shall construct such source so that it will operate in compliance with this Subpart.

(Source: Added at ___ Ill. Reg. _____, effective _____)

IT IS SO ORDERED

I, Dorothy M. Gunn, Clerk of the Illinois Pollution Control Board, hereby certify that the above Proposed Rule, Second Notice Opinion and Order was adopted on the 4th day of February, 1987, by a vote of 7-0.

Dorothy M. Gunn

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board