

ILLINOIS POLLUTION CONTROL BOARD
October 19, 1995

REXAM MEDICAL PACKAGING)	
INC. (formerly DRG)	
MEDICAL PACKAGING INC.),)	
)	
Petitioner,)	
)	
v.)	PCB 95-99
)	(Variance-Air)
)	
ILLINOIS ENVIRONMENTAL)	
PROTECTION AGENCY,)	
)	
Respondent.)	

TIMOTHY J. RACHKE, APPEARED ON BEHALF OF PETITIONER;

SHEILA G. KOLBE APPEARED ON BEHALF OF THE RESPONDENT.

OPINION AND ORDER OF THE BOARD (by R. C. Flemal):

This matter comes before the Board upon a petition for variance filed by Rexam Medical Packaging Inc. (Rexam)¹. Rexam requests variance from certain control requirements applicable to emissions of volatile organic material (VOM) from Rexam's flexographic printing presses located at 1919 South Butterfield Road, in Mundelein, Lake County, Illinois. Rexam is requesting that the term of the variance be from March 15, 1995 until June 15, 1996.

The Board's responsibility in this matter arises from the Environmental Protection Act (Act) (415 ILCS 5/35 (1994)). The Board is charged there with the responsibility of granting variance from Board regulations whenever it is found that compliance with the regulations would impose an arbitrary or unreasonable hardship upon the petitioner. (415 ILCS 5/35(a) (1994).) The Agency is required to appear in hearings on variance petitions. (415 ILCS 5/4(f) (1994).) The Agency is also charged, among other matters, with the responsibility of investigating each variance petition and making a recommendation to the Board as to the disposition of the petition. (415 ILCS 5/37(a) (1994).)

¹ At hearing on August 18, 1995, petitioner filed a "Name Change Form" as Exhibit #5 indicating that DRG Medical Packaging Inc. had changed its name to Rexam Medical Packaging Inc. The Board has changed the caption in this proceeding to reflect the change. Petitioner herein will be referred to as Rexam.

As presented below, the Board finds that Rexam has met its burden of demonstrating that immediate compliance with the Act or Board regulations at issue would result in an arbitrary or unreasonable hardship. Accordingly, the variance request will be granted, subject to certain conditions.

PROCEDURAL HISTORY

Rexam filed the petition in this matter with the Board on March 14, 1995. Rexam requests variance from Board regulations requiring flexographic printing operations, for which there is potential to emit 25 tons per year (TPY) or more of VOM, to employ reasonably available control technology (RACT) on or before March 15, 1995. The regulations are found at 35 Ill. Adm. Code 218.Subpart H, consisting of Sections 218.401 through 218.404²; the compliance date is separately found at 35 Ill. Adm. Code 218.106(c).

Pursuant to 35 Ill. Adm. Code 104.180(a), the Agency's statutory recommendation was originally due on April 29, 1995. On April 12, 1995, the Agency filed a motion for extension of time to file the recommendation seeking an extension until May 15, 1995, which the Board granted on April 20, 1995. On May 17, 1995, the Agency filed a second motion for extension of time seeking an extension until July 17, 1995. The Board granted this motion on May 25, 1995.

On July 17, 1995, the Agency filed its recommendation, wherein it recommends that the variance be granted subject to certain conditions. Rexam and the Agency subsequently submitted a revised set of conditions (see Exh. #4) which they contend are appropriate if the variance is to be granted. (Tr. at 6, 38.)³

A hearing was held on August 18, 1995 in Libertyville, Illinois before Board hearing officer June Edvenson. In addition to testimony, the parties entered six exhibits. The parties waived their right to submit briefs.

² Subpart H includes regulations applicable to printing and publishing generally. Only the cited sections pertain to flexographic printing operations.

³ The transcript will be cited as (Tr. at __); the petition will be cited as (Pet. at __); the Agency recommendation will be cited as (Rec. at __); and Exhibits will be cited as (Exh. #__).

STATUTORY FRAMEWORK

In determining whether any variance is to be granted, the Act requires the Board to determine whether a petitioner has presented adequate proof that immediate compliance with the Board regulation at issue would pose an arbitrary or unreasonable hardship. (415 ILCS 5/35(a) (1994).) Furthermore, the burden is on petitioner to show that its claimed hardship outweighs the public interest in attaining immediate compliance with regulations designed to protect the public. (Willowbrook Motel v. Pollution Control Board (1st Dist. 1977), 135 Ill.App.3d 343, 481 N.E.2d 1032). Only with such a showing can the claimed hardship rise to the level of arbitrary or unreasonable hardship. (We Shred It, Inc. v. Illinois Environmental Protection Agency, (November 18, 1993), PCB 92-180 slip op. at 3.)

A further feature of a variance is that it is, by its nature, a temporary reprieve from compliance with the Board's regulations, and compliance is to be sought regardless of the hardship which the task of eventual compliance presents an individual polluter. (Monsanto Co. v. Pollution Control Board, (1977), 67 Ill.2d 276, 367 N.E.2d 684.) Accordingly, except in certain special circumstances, a variance petitioner is required as a condition to the grant of a variance, to commit to a plan which is reasonably calculated to achieve compliance within the term of the variance.

The regulations that are the subject of the instant variance request were adopted by the Board in 1994 in docket R93-14. (In the Matter of: Reasonably Available Control Technology for Major Sources Emitting Volatile Organic Materials in the Chicago Ozone Nonattainment Area: 25 Tons (Amendments to 35 Ill. Adm. Code Parts 211 and 218), (January 6, 1994).) The purpose of limiting VOM emissions is to reduce the quantity of ozone in the lower atmosphere. Ozone is a significant air pollutant that forms through interactions of VOM with sunlight and oxygen, particularly during the warm weather months.

BACKGROUND

Rexam manufactures sterilizable flexible packaging and film products such as bags, pouches, and rollstock for sterilization protection of medical devices and products. The products are sold to medical providers, and are designed to be used in sterilization processes. (Pet. at 3; Tr. at 12.)

The packaging products contain printing, such as instructions on how to use the package and the type of product the package may hold. (Exh. #3 at 4.) Among special requirements are that the inks used in the printing process

adhere to the packaging in order to prevent contamination of the medical device product. (*Id.*)

Among other unusual features is the need for special inks used as sterilization indicators. Rexam's products go through a sterilization procedure to insure that they are contamination-free. (Tr. at 13.) The indicator ink for sterilization consists of a dual purpose ink which changes color to show that sterilization has occurred. Thus, a medical professional can verify by looking at the package that the products in the package have been sterilized. (Exh. #3 at 4.) Rexam also sterilizes reusable medical equipment that is placed in the pouches. (Tr. at 14.)

VOM emissions result from the vaporization of solvents used in the printing process and, to a lesser degree, in cleaning the printing presses. (Pet. at 3.) The VOM discharge points are the plant's dryer exhaust stacks and the general building exhaust ventilated into the atmosphere. (*Id.*) Rexam's total current VOM emissions are estimated to be 36 TPY. (Rec. at 3.)

Most of Rexam's printing operations are presently in compliance with the pertinent RACT regulations. However, six of Rexam's presses remain out of compliance. Rexam requests the instant variance to allow it to continue operations on these presses while it completes its RACT compliance obligations.

DISCUSSION

Compliance Status

Rexam began searching for compliance methods, including the use of lower VOM inks, in 1990. (Tr. at 19.) The company undertook its first conversion to low-VOM inks in 1991 when it replaced 40% VOM ink with 3.5% VOM ink for part of its product line. (*Id.*) In addition, in late 1991 and early 1992 the company began looking at water-based systems for roll film processing. (*Id.*) Changing to a water-based system in this area required a new process and the company changed its anilox rollers used to transfer the ink onto the imaging plate and onto the film from chrome to ceramic. (Tr. at 20.) Rexam also changed its fountain roll system and pumps for use in a water-based system. During 1993 the company experimented with the new system and by the end of 1994 it had ten extrusion lines converted to water-based systems. (Tr. at 20-21.) From 1990 to the date of the hearing, the company has spent a little over one million dollars to convert to low-VOM inks and to purchase control devices. (Tr. at 22.)

By March of 1995, thirteen of Rexam's presses had been converted to water-based inks in compliance with Section

218.401(a). (Tr. at 24.) However, five other flexographic presses could not reach compliance by March 15, 1995 because they were awaiting final customer product approval prior to conversion to water-based indicator inks.

Rexam contends that customer product approval requires a lengthy validation and testing trial period. (Tr. at 24.) Nevertheless, No. 107 has now been converted and off-line 36 inch press will be converted by December 1995. (Tr. at 25.) The proposed catalytic oxidizer for presses running solvent-based indicator inks will complete the compliance program. (Tr. at 25.)

Compliance Plan

Rexam proposes to achieve compliance principally through the installation and use of a catalytic oxidizer to control emissions from four of its presses (press No. 105, press No. 111, offline 32-inch press, and offline 42-inch press), and the conversion the fifth press (offline 36-inch press) to water-based ink. Rexam additionally commits to connecting the fifth press to the oxidizer if that press is not converted to water-based ink by March 1, 1996.

The Agency and Rexam estimate the cost of the control equipment at \$277,991, excluding taxes, freight, hood capture system, installation cost, special temperature monitors, performance testing, environmental consulting, and permitting fees, or any other additional costs. (Rec. at 5 and Pet. at 7.)

Environmental Impact and Compliance with Federal Law

Rexam's compliance program should allow Rexam to reduce its VOM emissions to below 25 TPY, as required by regulation. Moreover, because the program is to be completed prior to the beginning of the 1996 warm weather months, both Rexam and the Agency contend that grant of variance would have no effect on ozone levels during the coming and future ozone seasons⁴. (Tr. at 37.)

The Agency also observes that, because the control equipment will be installed by the 1996 ozone season, the granting of the variance will not impede the State's efforts in achieving the 15% reduction in VOM emissions required by Section 182(b)(1) of the Clean Air Act (42 U.S.C. 7511 (b)(1)). (Rec. at 6.)

⁴ The ozone season is the annual period from April 1 to October 31.

Prior to achieving compliance, Rexam contends that it will continue to emit 3 tons of VOM per month. The Agency believes that during the winter months these VOM emissions will have a minimal impact on ozone air quality. (Rec. at 4.)

Hardship

Rexam asserts that in the absence of grant of variance it would suffer an economic hardship not justified by the minimal environmental impact. Rexam contends that denial of variance would lead to loss of sales totaling approximately 11 million dollars (Tr. at 28) plus the loss of 75 jobs (Tr. at 29).

Additionally, Rexam believes that its customers would have problems gaining alternative supplies due to product shortages that Rexam's competitors may not be able meet. Rexam observes that product shifting is not always possible because of the stringent customer specifications and sterilization requirements of the medical industry.

Rexam contends that technology for indicator inks converting to water-based inks is not proven and that in order for customers to use the products the Federal Drug Administration must indicate that they are both safe and effective. (Tr. at 27; Pet. at 5.) To accomplish this there must be assurance that the inks used for sterility indication change in a detectible way. (Tr. at 27.)

CONCLUSION

In determining whether any variance is to be granted, the Act requires the Board to determine whether a petitioner has presented adequate proof that immediate compliance with the Board regulations at issue would impose an arbitrary or unreasonable hardship upon the petitioner. (415 ILCS 5/35(a) (1994).) Furthermore, the burden is on the petitioner to show that its claimed hardship outweighs the public interest in attaining compliance with regulations designed to protect the public. (Willowbrook Motel v. IPCB (1985), 135 Ill.App.3d 343, 481 N.E.2d 1032.) Only with such a showing can the claimed hardship rise to the level of arbitrary or unreasonable hardship.

The Board agrees with the Agency that Rexam's emissions during the term of the proposed variance will have a negligible environmental impact during the 1996 ozone season because compliance with all emission limitations will be completed before the ozone season begins. Therefore, based upon the record before it and upon review of the hardship petitioner would encounter, and the fact that there will be no environmental impact for the 1996 ozone season that would result from grant of variance, the Board finds that petitioner has presented adequate proof that immediate compliance with the regulations at issue would result

in an arbitrary or unreasonable hardship. The variance accordingly will be granted.

Petitioner has requested that the variance commence on March 15, 1995 and end on June 15, 1996. The Board notes that it is well established practice that the term of a variance begins on the date the Board renders its decision unless unusual or extraordinary circumstances are shown. (See DMI, Inc. v. IEPA, (December 19, 1991) PCB 90-227, 128 PCB 245-249.)

The Board believes that Rexam has shown unusual circumstances in this case. Rexam's delay in compliance is not self-imposed, but rather is due to the special and stringent requirements placed upon its products. Moreover, the Board believes that Rexam has conscientiously attempted to achieve compliance, and that it is firmly committed to the final steps necessary to do so.

The Board notes that Rexam requests that the variance extend until June 15, 1996, even though Rexam commits to taking all actions necessary for achieving the needed emissions reductions prior to March 1, 1996. The additional time is requested to allow Rexam opportunity to complete and submit to the Agency a "certification of compliance", as required pursuant to 35 Ill. Adm. Code 218.Subpart H. The Board finds that it is appropriate to extend the term of the variance for this limited purpose.

Lastly, the Board has reviewed the conditions that Rexam and the Agency jointly submit (Exh. #4), most of which are in the nature of a compliance schedule. The Board agrees that the conditions are necessary to the grant of variance, and accordingly they will be included within the variance order.

This opinion constitutes the Board's findings of fact and conclusions of law in this matter.

ORDER

Rexam Medical Packaging Inc. is hereby granted a variance for its flexographic printing presses located at 1919 South Butterfield Road, in Mundelein, Lake County, Illinois from 35 Ill. Adm. Code 218.106(c), 218.401, 218.402, 218.403, and 218.404, subject to the following conditions:

- 1) This variance is effective beginning on March 15, 1995. It terminates on June 15, 1996, or thirty (30) days after submittal of the 35 Ill. Adm. Code.Subpart H "certification of compliance", whichever is first.
- 2) Rexam shall complete installation and commence operation of the catalytic oxidizer by March 1, 1996.

Flexographic printing lines controlled by the catalytic oxidizer must include Press No. 105, Press No. 111, Offline 32-inch press, and the new Offline 42-inch press.

- 3) Rexam shall complete performance testing of the catalytic oxidizer by April 15, 1996. Performance testing must include determination of the VOM reduction efficiency capture system and control equipment. Rexam shall submit results of the performance testing to the Illinois Environmental Protection Agency by June 15, 1996.
- 4) Rexam shall complete water-based ink conversion for the flexographic printing Offline 36-inch press by March 1, 1996. If the line is not converted by this date, it must be connected to the catalytic oxidizer by March 1, 1996.
- 5) Rexam shall submit to the Illinois Environmental Protection Agency a "certification of compliance" with 35 Ill. Adm. Code Subpart II regulations required pursuant to Section 218.404 by June 15, 1996.
- 6) Upon receipt of the construction permit for the catalytic oxidizer, Rexam shall send quarterly status reports to the Illinois Environmental Protection Agency on the progress of the installation and testing of the control equipment, with the following information:
 - a. Dates when installation begins and ends;
 - b. Test results; and
 - c. Any correspondence from the control equipment manufacturer indicating pending delay.
- 7) Rexam shall notify the Illinois Environmental Protection Agency that physical installation of the catalytic oxidizer is complete within ten (10) days of the completion date.
- 8) Rexam shall notify the Illinois Environmental Protection Agency when full-time operation of the catalytic oxidizer has commenced within ten (10) days of control equipment start up date.
- 9) Rexam shall notify the Illinois Environmental Protection Agency that conversion to water-based ink for the flexographic printing Offline 36-inch press is complete within ten (10) days of completion date of such conversion.

- 10) When Rexam commences operation of the catalytic oxidizer and completes water-based conversion for the Offline 36-inch press, before March 1, 1996, petitioner is to send a status report within ten (10) days to the Illinois Pollution Control Board and a copy to the Illinois Environmental Protection Agency.
- 11) When Rexam completes performance testing of the catalytic oxidizer and submits performance test results and required Subpart H certification of compliance to the Illinois Environmental Protection Agency, before June 15, 1996, Rexam is to send a status report within ten (10) days to the Illinois Pollution Control Board and a copy to the Illinois Environmental Protection Agency.
- 12) All notifications to the Illinois Environmental Protection Agency required by the terms of this variance are to be sent to:

David Kolaz, P.E.
Manager, Compliance & Systems Management Section
Division of Air Pollution Control
Box 19276
Springfield, IL 62794-9276

IT IS SO ORDERED.

If Rexam chooses to accept this variance subject to the above order, within 45 days of the date of this order Rexam shall execute and forward to:

Sheila Kolbe
Division of Legal Counsel
Illinois Environmental Protection Agency
P.O. Box 19726
2200 Churchill Road
Springfield, Illinois 62794-9276

a Certification of Acceptance and Agreement to be bound to all terms and conditions of this variance. The 45-day period shall be held in abeyance during any period that this matter is being appealed. Failure to execute and forward the Certificate within 45 days renders this variance void and of no force and effect as a shield against enforcement of rules from which variance was granted. The form of said Certification is as follows:

CERTIFICATION

I (We), _____,
hereby accept and agree to be bound by all terms and conditions

of the order of the Pollution Control Board in PCB 95-99, October 19, 1995.

Petitioner _____

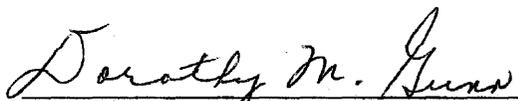
Authorized Agent _____

Title _____

Date _____

Section 41 of the Environmental Protection Act (415 ILCS 5/41 (1994)) provides for the appeal of final Board orders within 35 days of the date of service of this order. The Rules of the Supreme Court of Illinois establish filing requirements. (See also 35 Ill. Adm. Code 101.246 "Motions for Reconsideration".)

I, Dorothy M. Gunn, Clerk of the Illinois Pollution Control Board, hereby certify that the above opinion and order was adopted on the 19th day of October, 1995 by a vote of 7-0.



Dorothy M. Gunn, Clerk
Illinois Pollution Control Board