

MOST HEALTH SERVICES, INC. :
 :
 : **v.** : **EHB Docket No. 2007-069-MG**
 :
 : **COMMONWEALTH OF PENNSYLVANIA,** :
 : **DEPARTMENT OF ENVIRONMENTAL** : **Issued: May 6, 2008**
 : **PROTECTION** :

ADJUDICATION

By Michelle A. Coleman, Judge

Synopsis:

The Board agrees with the \$80,500 civil penalty assessed by the Department against the operator of a mobile X-ray unit company for taking X-rays as part of a screening program without a prescription or approval from the Department of Environmental Protection. There is no doubt that the actions taken by the operator violate the Department’s regulations under the Radiation Protection Act, therefore the penalty assessed by the Department is a reasonable fit to the circumstances of the violation. Accordingly, the Board upholds the penalty of \$80,500.

BACKGROUND

Before the Board is an appeal of Most Health Services, Inc. (MHI or Appellant) challenging a civil penalty assessment by the Department of Environmental Protection pursuant to the authority of the Radiation Protection Act which was filed on February 22, 2007. MHI argues that the amount of the penalty, \$80,500, is excessive and constitutes an abuse of discretion by the Department.

A hearing was held on December 4, 2007, before the Honorable George J. Miller. The

record consists of a transcript of 171 pages and eight exhibits. Both parties filed post-hearing memoranda which included proposed findings of fact and conclusions of law. After full consideration of these materials we make the following:

FINDINGS OF FACT¹

1. The Department is the agency with the duty and authority to administer and enforce the Radiation Protection Act, Act of July 10, 1984, P.L. 688, *as amended*, 35 P.S. §§ 7110.101-7110.703 (Act); Section 1917-A of the Administrative Code, Act of April 9, 1929, P.L. 177, *as amended*, 71 P.S. § 510-17; and the rules and regulations promulgated thereunder. (Stip. ¶ 1)

2. Since 1988 MOST Health Services, Inc. (MHI or Appellant) has been a Pennsylvania corporation which at all relevant times operated out of offices at 501 Preston Avenue, Voorhees, NJ 08043. (Stip. ¶ 2)

3. MHI was predominantly engaged in the enterprise of sending staff and equipment to various business customers to conduct health screenings, primarily concerning asbestosis. (Stip. ¶ 3)

4. At all relevant times MHI possessed for use in its mobile screening business a movable X-ray unit, which MHI duly registered with the Department's Bureau of Radiation Protection (Bureau) as a New Jersey-based, out-of-state, radiation source. (Stip. ¶ 4)

5. MHI's movable X-ray unit was and is a 300 milli-ampere, 120 kilovolt dedicated chest X-ray unit. (Stip. ¶ 5)

6. Since 1991, Mr. Charles Kemeny has been president and 46% shareholder of MHI. (Stip. ¶ 6)

7. Mr. Kemeny is one of two MHI officers responsible for familiarity and company

¹ References to the transcript are abbreviated as "N.T. ___". The parties submitted a stipulation of facts which was admitted into the record as Ex. B-1. The stipulations are referenced as "Stip. ¶ ___." The Department's exhibits are designated "Ex. C-___" and MHI's as "Ex. A-___."

compliance with government regulations. (Stip. ¶ 7)

8. In late 2001 or early 2002, Mr. Kemeny was approached by Texas law firm Provost Umphry for the purpose of setting up mass chest X-rays by MHI at union hall sites in Pennsylvania. (Stip. ¶ 12)

9. MHI contracted with Provost Umphry to take two X-rays of each union member who showed up at each site; a lateral (side) view and a P-A (posterior-to-anterior or back-to-front) view. (Stip. ¶ 13)

10. In accordance with its contract with Provost Umphry, MHI conducted the first series of X-rays on February 19, 2002 at a Best Western motel in Harrisburg, Dauphin County. MHI conducted the second series of X-rays on February 21, 2002 at the Woodlands Inn and Resort in Wilkes-Barre, Luzerne County, and the third series on February 23, 2002 at the Comfort Inn in Essington, Delaware County (collectively, “the mass X-rays”). (Stip. ¶15)

11. The mass X-rays were administered without the knowledge, authorization or approval of the Department. They were also conducted without the authorization or the presence of a licensed practitioner of the healing arts. The total number of these humans exposed was 161 persons. (Stip. ¶ 16).

12. Mr. Kemeny testified that he was unaware that he had to obtain authorization from the Department or a prescription from a licensed practitioner of the healing arts to take X-rays in Pennsylvania. (N.T. 119)

13. He also testified that a prescription by a practitioner of the healing arts would not have changed the manner in which the X-rays were taken nor would obtaining a prescription have generated a cost to MHI. (Kemeny, N.T. 125-27)

14. James G. Yusko of the Department’s Southwest Regional Office, testified as an expert in radiation health. He testified that there are health risks associated with exposure to

radiation from X-rays, although there are also diagnostic benefits to the procedure which often outweigh the risks. Accordingly, the Department has implemented a policy of limiting exposure to “as low as reasonably achievable” or “ALARA.” (N.T. 13, 15-23)

15. Generally speaking, the preferred method of performing chest X-rays is from back to front, or posterior to anterior, because it reduces the shadow of the heart and reduces the intensity of radiation exposure for women. (Yusko, N.T. 25)

16. Some of the risks associated with improperly performed X-rays include the economic and physiologic risk of a “false negative” or “false positive.” A “false positive” is an identification of a disease that is not, in fact present. A “false negative” is when a disease is present but not identified. (Yusko, N.T. 22-23)

17. There is no evidence that the MHI X-rays were taken improperly or resulted in any false negative or false positive readings. (Craig, N.T. 89-90)

18. Bridget Craig, an environmental protection compliance specialist in the Department’s Bureau of Radiation Protection, calculated the civil penalty. (Craig, N.T. 73)

19. The MHI matter was brought to her attention by her supervisor, Terry Derstine, the Program Manager for the Bureau of Radiation Protection in the Department’s Southeast Regional Office. He had received an anonymous complaint that MHI had taken X-rays without authorization in the form of a transcript of a video deposition of Mr. Kemeny. He referred the matter to Ms. Craig and asked her to review the information and make a recommendation. (Derstine, N.T. 38-41; Craig, N.T. 73-74)

20. Ms. Craig recommended that the Department issue a notice of violation and hold an enforcement conference with MHI. As a result of the conference, the Department decided on a unilateral assessment of civil penalty. (Derstine, N.T. 38-41; Craig, N.T. 73-74)

21. The penalty was based on MHI’s failure to secure prescriptions for the X-rays or

authorization from the Department to perform X-rays without a prescription. (Notice of Appeal, Attachment A²; 25 Pa. Code §§ 221.11(g) and 221.11(g)(2).

22. Ms. Craig consulted the Bureau's enforcement policy and civil penalty matrix to develop her civil penalty. (Craig, N.T. 75; Ex. C-3)

23. Her penalty calculation was based on the severity of the violation, and the level of culpability of MHI. She then took into account the lack of actual damage and the lack of economic benefit to MHI for failing to get prescriptions from a practitioner of the healing arts for the X-rays. (Craig, N.T. 77-83; 87-88)

24. The penalty matrix provides three levels of severity for a violation of the Radiation Protection Act and regulations. A Level I violation is one that results in physical injury and is the most serious level of violation. A Level II violation is one that creates a potential for injury. Level III is the least serious violation and is for paperwork or clerical violations. Ms. Craig concluded that MHI's violation created a potential injury to human health because there was evidence of exposure to radiation without a good reason. (Craig, N.T. 77-78; Ex. C-3)

25. The matrix also assesses four levels of culpability: wilfull, reckless, negligent and accidental. Ms. Craig determined that MHI's conduct was reckless because the company is a registered company in Pennsylvania and should have been aware of the regulations that require either a prescription or authorization from the Department to perform X-rays within the Commonwealth. (Craig, N.T. 78-80)

26. A Level II violation with a culpability assessment of "reckless" results in a penalty of \$5,000 - \$10,000 per violation. Ms. Craig determined that \$5,000 per violation was appropriate. She multiplied \$5,000 by 161 unauthorized X-rays and reached an initial penalty calculation of \$805,000. (Craig, N.T. 81-83; Ex. C-3)

² Ex. B-2.

27. However, she felt that this amount was not a reasonable penalty amount given the circumstances of the violations. Accordingly, she reduced the penalty by 90% for a final calculation of \$ 80,500. (Craig, N.T. 83, 86-87; Notice of Appeal, Attachment A)

OPINION

In an appeal from a civil penalty assessment, the Department bears the burden of proof.³ Accordingly, the Department must prove by a preponderance of the evidence that the violations occurred and that the civil penalty assessed is lawful and reasonable given the circumstances of the violation.⁴ Our review is *de novo*; thus our decision is based upon the record developed before the Board.⁵ Where we find that a penalty is not a reasonable fit given the facts of the violation, we may adjust a penalty assessment accordingly.⁶

In this appeal, MHI does not challenge the fact of the violations. However, it argues that the amount of the penalty is excessive and should be reduced. As we explain below, we disagree.

MHI does not challenge the Department's conclusion that it violated the Department's regulations by taking X-rays without either a prescription or an approval from the Department.⁷ MHI admits that it neither had a prescription, as required by 25 Pa. Code § 221.11(g), nor

³ 25 Pa. Code § 1021.122(b)(1).

⁴ *See, e.g., Benacci v. DEP*, 2005 EHB 560.

⁵ *Id.*

⁶ *Keinath v. DEP*, 2003 EHB 43.

⁷ Section 221.11(g) provides:

(g) An individual may not be exposed to the useful beam except for healing arts purposes or under § 221.15 (relating to use of X-rays in research on humans). An exposure shall be authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration or other nonhealing arts purposes.

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by the Department. When requesting authorization, the registrant shall submit the information outlined in § 221.13 (relating to information to be submitted by persons requesting approval to conduct healing arts screening).

authorization from the Department to perform the X-ray screenings under Section 221.11(g)(2).⁸ Therefore, we find that the Department sustained its burden of proving that there was a violation of the regulations. It was appropriate to initiate enforcement action as authorized by the Radiation Protection Act.

The Radiation Protection Act⁹ authorizes the Department to assess civil penalties:

In addition to proceeding under any other remedy available at law or in equity for a violation of this act or a regulation or order of the department promulgated or issued hereunder, the department may assess a civil penalty upon the person for the violation. This penalty may be assessed whether or not the violation was willful or negligent. The civil penalty shall not exceed \$ 25,000 plus \$ 5,000 for each day of continued violation. In determining the civil penalty, the department shall consider, where applicable, the willfulness of the violation, gravity of the violation, good faith of the person charged, history of the previous violations, danger to the public health and welfare, damage to the air, water, land or other natural resources of the Commonwealth or their uses, cost of restoration or abatement, savings resultant to the person in consequence of the violation and any other relevant facts.¹⁰

To implement the directives of the act, the Department utilizes a penalty policy which creates a matrix which consists of twelve ranges of penalties based upon the gravity of a particular violation and the level of culpability of the violator. Each level of penalty “discounts” the maximum penalty of \$ 25,000 per day of violation.¹¹

Although the Board has found the Department’s penalty matrices helpful as a starting point in our analysis of a civil penalty, we are not bound by it.¹² Rather, the purpose of our review is to determine whether the Department correctly applied the criteria of the Radiation Protection Act and whether the resulting penalty is reasonable and appropriate.¹³

⁸ Stip. ¶ 16.

⁹ Radiation Protection Act, Act of July 10, 1984, P.L. 688, 35 P.S. §§ 7110.101-7110.703.

¹⁰ 35 P.S. § 7110.308(e).

¹¹ Ex. C-3, pp. 32-37.

¹² *Clearview Land Development Co. v. DEP*, 2003 EHB 398; *Keinath v. DEP*, 2003 EHB 43.

¹³ *Sunoco, Inc. (R&M) v. DEP*, 2004 EHB 191, *affirmed*, 865 A.2d 960 (Pa. Cmwlth. 2005).

Ms. Craig arrived at the \$80,500 penalty by choosing a penalty range for a violation that created a potential injury to human health as a result of reckless conduct. According to the matrix, the range for such a violation was \$5,000 to \$10,000. She began with a \$5,000 penalty and multiplied it by 161 individuals who were X-rayed, which resulted in an initial calculation of \$805,000. Recognizing that this amount was not a reasonable fit, she discounted the penalty by 90% to arrive at \$80,500. The Board finds Ms. Craig's process to be reasonable and therefore agrees with the Department's assessment.

Although the Board may disagree with the Department's characterization of MHI's culpability as reckless we will not adjust the penalty in this matter. Ms. Craig stated that a level of negligence could be described as someone who was not very careful and violated the regulation.¹⁴ Mr. Kemeny admits to not reading or being familiar with the Commonwealth's regulations concerning the use of X-ray units in Pennsylvania. This type of behavior was not "very careful." However, "reckless" is a conscious disregard of the fact that conduct may result in a violation of the law. "Negligence" is a failure to exercise reasonable care.¹⁵ There is no evidence on the record that Mr. Kemeny was deliberately unaware of the regulatory requirements for authorization to X-ray individuals or that he had received warnings from the Department and ignored them. He testified that he had nothing to gain by not getting prescriptions or an authorization, inasmuch as it would not have added to his expenses nor would it have changed the manner in which the X-rays were taken.¹⁶ Therefore he had no reason to ignore the requirement. Rather, he simply failed to make himself aware of the requirements.

¹⁴ N.T. 79.

¹⁵ See, e.g., *202 Island Car Wash, L.P. v. DEP*, 2000 EHB 679.

¹⁶ N.T. 125-27.

However, ignorance of the law is no excuse for violating the law.¹⁷ There was no testimony that it would have been especially difficult for Mr. Kemeny to have informed himself about the regulatory requirements for performing X-rays within the Commonwealth. We agree with the Department that it has a significant interest in the regulation of radiation sources. Further, Mr. Yusko stressed the importance of the Department being aware of the presence of out-of-state X-ray providers doing business within the Commonwealth in order to make sure that X-rays are being performed in such a way as to minimize the risk caused by radiation exposure.¹⁸ So it is clear that a substantial penalty is appropriate. We will not adjust the \$80,500 penalty even though we believe MHI's culpability is more consistent with negligence rather than recklessness. Since the DEP reduced the calculated penalty by 90%, which is substantially less than the assessed penalty under negligence using the Department's matrix, we will not adjust the penalty.

The Board is extremely concerned that MHI took x-rays of 161 people on two occasions without following the law. We are aware that radiation exposure to humans poses health risks and that this type of activity must gain all prior approvals before being conducted within our Commonwealth. We believe that the \$80,500 civil penalty is reasonable and not excessive.

We therefore make the following:

CONCLUSIONS OF LAW

1. The Board's scope of review is *de novo*. *Benacci v. DEP*, 2005 EHB 560.
2. In an appeal of a civil penalty, the Department bears the burden of proof. 25 Pa. Code § 1021.122(b)(1).

¹⁷ *E.g.*, *Enterprise Tire Recycling v. DEP*, 1999 EHB 900 (appellant's assertion that it did not know it needed a permit for a solid waste activity is not a defense to the Department's compliance order.)

¹⁸ N.T. 19-20.

3. The Appellant, MHI, violated Section 221.11(g) of the Department's radiation protection regulations by performing X-rays without a prescription from a licensed practitioner of the healing arts or authorization from the Department to perform health screenings. 25 Pa. Code § 221.11(g).
4. The assessment of a civil penalty is authorized by the Radiation Protection Act. 35 P.S. § 7110.308(e).
5. The \$ 80,500 penalty assessed by the Department is a reasonable fit for MHI's violation of the Department's radiation protection regulations.

We therefore enter the following:



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ORDER

AND NOW, this 6th day of May, 2008, the appeal of Most Health Services, Inc. is sustained in part consistent with the above adjudication. Most Health Services Inc. shall pay a civil penalty in the amount of **\$80,500**. The amount is due and payable immediately to the Commonwealth of Pennsylvania, Radiation Protection Fund. The appeal is dismissed in all other respects.

ENVIRONMENTAL HEARING BOARD

THOMAS W. RENWAND
Acting Chairman and Chief Judge

MICHELLE A. COLEMAN
Judge

BERNARD A. LABUSKES, JR.
Judge

A Concurring Opinion of Judge Bernard A. Labuskes, Jr. is attached. A Dissenting Opinion of Judge George J. Miller is attached.

DATED: May 6, 2008

c: DEP Bureau of Litigation
Attention: Brenda K. Morris, Library

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CONCURRING OPINION

I concur in the majority opinion. I cannot disagree that a penalty of \$80,500 is a reasonable fit. I write separately and briefly to outline why I believe that a much higher penalty could also have been justified in this case.

Under the scheme hatched by MHI and the Texas law firm of Provost Umphry, the decisions concerning who would be X-rayed, the number and orientation of X-rays taken, and whether additional tests were to be taken were made solely by Provost Umphry, not by medical practitioners. The mass X-rays were conducted without any health professionals having any involvement whatsoever. Patients were advised that they could be retested even if they had previously been tested and found negative within the past few years, but they were not warned that they might have been X-rayed too recently to be safely reexposed so soon. MHI did not require the patients to show identification before they were X-rayed. MHI did not ask the patients the date of their last chest X-ray. Before X-raying, Provost Umphry did not inquire of the patients as to their medical history, but it did make sure to have them sign contingent fee agreements respecting occupational exposure litigation.

Exposure to radiation can obviously have serious consequences. Radiation is a known human carcinogen, and there is no known safe level of exposure to it. Accordingly, there are

only two circumstances in which X-ray machines may be used on humans. The first is in compliance with a prescription given by a licensed practitioner of the healing arts. The second is in accordance with a general screening program that has been designed by a physician and has been preapproved by the Department after review in consultation with additional medical practitioners. In either case, a health professional's involvement is critical. The goal in either case in requiring a health professional's involvement is to prevent *exactly* the sort of thing that happened here.

I believe that the penalty could have been much higher in this case for several reasons. First, for a company that is in the business of giving X-rays to assert that it is not familiar with the law regarding the giving of X-rays is unbelievable and unacceptable. If a landfill owner came before this Board and professed ignorance regarding the laws regarding solid waste disposal, it would have been laughed out of court. It is inconceivable that the operator of equipment potentially dangerous to human health would claim such ignorance of applicable laws.

The laws in question have been on the books since at least 1987. We are not dealing here with an obscure regulation or some byzantine guidance document. Furthermore, that X-rays should only be given under a health professional's direction strikes me as common sense and common knowledge. My guess is that the average fifth-grader knows that you need to see a doctor before you get an X-ray.

Exposure to X-rays, especially chest X-rays, should not be trivialized. X-rays are only indicated if a patient has symptoms or there is some other reason that the potential benefits of a diagnostic aid outweigh the known risks. At the risk of stating what should be obvious, that is precisely why prescriptions are required.

This case is no different than a pharmacist handing out potentially dangerous drugs with

known side-effects at the county fair without prescriptions. No one would think twice if the pharmacist were assessed a civil penalty of five hundred dollars or more for each incident.

X-rays are to be given for healing purposes, not to search out potential plaintiffs for tort litigation. MHI's violations strike at the heart of the radiation protection program, a program in which Pennsylvania has recently dramatically increased its role by becoming an Agreement State. If a nuclear power plant has a minor leak with no known human exposure, it does and should make front-page news. Here, 161 people were deliberately exposed with the only apparent purpose being to find toxic tort plaintiffs.

MHI claims it made no money as a result of the lack of prescriptions. In fact it would not have made *any* money if it had followed the law because no reputable doctor would have sanctioned what MHI did here. It was not necessary for the Department to prove the negative that a doctor would *not* have written prescriptions for some or all of the patients, just as it would not be necessary for prosecutors proceeding against our hypothetical pharmacist at the county fair to prove that a doctor would *not* have written a prescription for any of the fair goers. It was not necessary to prove that ill effects in any patients have been observed to date. All of these arguments miss the fundamental point that persons cannot be allowed to set up stands for free X-rays either at county fairs, or here, in hotel rooms, with no approval or supervision by health professionals.

Each X-ray constituted a violation. MHI has conceded that point. Assessing a penalty on a daily basis instead of per violation would have been arbitrary and possibly even unlawful. It would be like saying that Bonnie and Clyde were only guilty of one bank robbery per day no matter how many stops they made that day. MHI is not entitled to a volume discount. Assessing one penalty per day regardless of whether one or one hundred violations occurred on that day makes no sense to me.



Our review of a penalty assessment is for a reasonable fit. We do not review the penalty and decide what might have been a more reasonable amount. The Department's assessment of one percent of the statutory maximum is an extremely tolerant penalty but I cannot disagree it falls within the range of reasonableness.

BERNARD A. LABUSKES, JR.
Judge



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**DISSENTING OPINION OF
JUDGE GEORGE J. MILLER**

By George J. Miller, Judge

I cannot agree that the assessed penalty is a reasonable fit for the violations proven at the hearing. The Department had the burden of proving that such a large penalty is justified. The Department presented no evidence that a physician would not have given the required prescriptions. Nor was there evidence that the Department would not have granted approval out-of-hand of such a mass screening if a proper application had been made. Indeed, Mr. Yusko testifying for the Department, indicated that approval could have been given for a mass screening, even though the resulting x-rays may have also been used by workers for litigation.

The appellant's evidence was that the screening was done according to procedures used in normal physician directed x-rays to minimize harm to the worker. While appellant is presumed to know that either Department approval or a prescription is required, he testified that appellant previously had performed a similar x-ray program of Department employees without a physician's prescription. While such a screening would be lawful because of the Department's request, this experience may have lulled appellant into believing that a screening of others might be done without a prescription. Even the majority opinion concedes that the appellant's conduct

was more reasonably described as “negligent” rather than “reckless.”

I also think that a 90% reduction of a penalty calculation based on the number of persons screened is a purely arbitrary decision designed to avoid the charge that a full penalty of \$25,000 per day of violation would be unreasonable. Indeed, the majority opinion relies on this reduction as making the penalty a reasonable fit without any explanation as to why such a reduction is reasonable under the circumstances. I believe that a penalty assessment based on the number of days of violations would be more appropriate. Such an assessment at least avoids such an arbitrary decision and seems to me to result in a more reasonable fit for the violations proven by the Department.

ENVIRONMENTAL HEARING BOARD

GEORGE J. MILLER
Judge