November 14, 1997

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	
	)	
MAGDY ELAMIR, M.D	)	IA-97-070
	)	
Newark, New Jersey	)	
	)	

NRC STAFF RESPONSE TO LICENSING BOARD ORDER

INTRODUCTION

On October 23, 1997, the Atomic Safety and Licensing Board ("Board") issued a Memorandum and Order (Request for Hearing and Stay of Proceeding), in which it deferred action on Dr. Elamir's request for a stay of proceedings. The Board stated that it took this action because it lacked information needed to discharge its responsibility to conduct the proceeding expeditiously, giving due consideration to the rights of all parties.

The Board asked the NRC Staff ("Staff"), which supported Dr. Elamir's motion in a filing dated October 21, 1997, to advise it about the details of any referral to the Department of Justice (DOJ) and of any criminal investigation of Dr. Elamir being conducted by the DOJ. The Board also asked the Staff to provide a realistic estimate of the time needed by the Department to determine whether or not to undertake a formal criminal investigation. This is the Staff's response to the Board's request.

BACKGROUND

On September 15, 1997, the NRC staff issued to Magdy Elamir, M.D., President and Owner of Newark Medical Associates, P.A., an "Order Superseding Order Prohibiting Involvement in NRC - Licensed Activities (Effective Immediately)."[1] 62 Fed Reg. 49536 (September 22, 1997). The Order prohibits Dr. Elamir from engaging in NRC-licensed activities for five years, requires him to inform the NRC of any NRC-licensed entity or entities in which Dr. Elamir is involved and prohibits such involvements, and requires him to provide a copy of the Order to all such NRC licensed entities. On October 4, 1997, Dr. Elamir filed both an "Answer of Dr. Magdy Elamir to the Commission's September 15, 1997 Order Superseding Order Prohibiting Involvement in NRC-Licensed Activities" and a "Demand for Hearing and Request for Stay of All Proceedings."

On October 15, 1997, an Atomic Safety and Licensing Board was established to preside over the proceeding. On October 21, 1997, the NRC staff filed a response in support of Dr. Elamir's stay request. On October 23, 1997, the Board asked the Staff to provide information regarding any referral to the Department of Justice and any criminal investigation of Dr. Elamir being conducted by the DOJ. The Board also asked the Staff to provide a realistic estimate of the time needed by the DOJ to determine whether or not to undertake a formal criminal investigation.

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[1] On that same date, the NRC staff made a board notification in the related case of Aharon Ben-Haim, Ph.D. The board notification transmits an inspection report dated September 5, 1997, concerning an inspection of Newark Medical Associates' NRC-licensed activities. The board notification is attached for the Board's information.

DISCUSSION

The attached affidavit of Bruce A. Levy, Assistant United States Attorney in the United States Attorney's Office for the District of New Jersey (Levy Affidavit), addresses the information requested by the Board in its October 23, 1997 Order. Mr. Levy attests that his office is currently conducting a criminal investigation concerning allegations of possible violations of federal criminal statutes by Newark Medical Associates, its owners and employees, including Dr. Magdy Elamir. Levy Affidavit at ¶ 2. These statutes include, but are not limited to, Title 18, United States Code, sections 371 (conspiracy), 1001 (false statement), 1341 (mail fraud), 1343 (wire fraud), and 1347 (health care fraud). *Id.*

Mr. Levy states that the pending criminal investigation involves the same factual allegations and many of the same individuals who would likely be witnesses in the administrative proceeding. Levy Affidavit at ¶ 3. The information provided to Mr. Levy by the NRC includes evidence that Dr. Elamir caused false statements to be submitted to the NRC and engaged in conduct that caused a licensee to be in violation of the NRC's requirements. *Id.* This evidence is outlined in the Office of Investigations' Report on Newark Medical Associates, P.A., which is in the possession of the DOJ and the NRC. *See* Levy Affidavit at ¶ 3.

Mr. Levy attests that Newark Medical Associates and certain individuals, including Dr. Elamir, are, or may become, targets of the criminal investigation. Levy Affidavit at ¶ 5. These individuals may in the pending civil proceeding use discovery, including depositions, interrogatories, and document production requests, to obtain information about and from persons who may be witnesses in the criminal investigation and who may later be subpoenaed

to appear before a federal Grand Jury. Levy Affidavit at ¶ 5. For example, discovery in the instant proceeding could lead to the disclosure of relevant documents in the NRC's possession, including the OI report. *See* Levy Affidavit at ¶ 4. Mr. Levy states that the administrative proceeding should be delayed for 120 days. Levy Affidavit at ¶ 7. Because of the time needed to conduct the criminal investigation and because of the potential for a Grand Jury investigation, 120 days is a reasonable amount of time.

CONCLUSION

As noted in its response of October 21, 1997, and for the reasons set forth above, the Staff does not object to Dr. Elamir's October 4, 1997 stay request.

Respectfully submitted,

Catherine L. Marco for
Ann P. Hodgdon
Counsel for NRC Staff

Dated at Rockville, Maryland
this 14th day of November, 1997

November 5, 1997

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	
	)	
MAGDY ELAMIR, M.D.	)	IA-97-070
	)	
Newark, New Jersey	)	

DECLARATION OF BRUCE A. LEVY, AUSA

1. I am employed by the United States Department of Justice and have served as an Assistant U.S. Attorney in the United States Attorney's Office for the District of New Jersey ("this Office") for the past six years. I am the Criminal Health Fraud Coordinator for this Office and my responsibilities include the investigation and prosecution of criminal health care fraud cases. I submit this affidavit in support of the NRC staff's response to the Atomic Safety and Licensing Board's ("Licensing Board") Order of October 23, 1997.

2. This Office has received information from the NRC, Office of Investigations, concerning allegations of possible violations of federal criminal law by Newark Medical Associates, P.A., including its president and owner, Magdy Elamir, M.D. (Dr. Elamir). The allegations presented relate to potential violations of several criminal statutes, including, but not limited to, Title 18, United States Code, Sections 371 (conspiracy), 1001 (false statement), 1341 (mail fraud), 1343 (wire fraud), and 1347 (health care fraud). This Office is presently conducting a criminal investigation with respect to these allegations.

3. The information provided by the NRC to this Office includes evidence that Dr. Elamir

caused false statements to be submitted to the NRC in connection with a License Application, and engaged in conduct that caused the licensee to be in violation of the NRC's requirements. Based on discussions with NRC's Office of Investigation, as well as a review of documents filed in this proceeding, it is my understanding that this Office's criminal investigation and this proceeding involve the same factual allegations and many of the same witnesses. The information referred to above is outlined in a report relating to Newark Medical Associates, P.A. prepared by the NRC, Office of Investigations ("the OI Report").

4. Based on discussions with counsel for the NRC, it is my understanding that discovery in the pending NRC proceeding that Dr. Elamir would be entitled to far exceeds the scope of discovery permitted by The Federal Rules of Criminal Procedure. For example, during federal criminal investigations witness statements are not made available to potential targets, subjects, or to anyone else not involved in the law enforcement function. Further, in the event an indictment is returned by a federal grand jury, pursuant to The Jencks Act (Title 18, United States Code, Section 3500), a defendant in a criminal case is generally not entitled to receive prior statements of a government witness until after s/he testifies. Should the pending proceeding continue, reports, such as the OI report, may be disclosed.

5. Newark Medical Associates, P.A., and certain individuals, including Dr. Elamir, are, or may become, subjects and/or targets of this Office's criminal probe.[1] These individuals may utilize the tools of discovery in this proceeding, including depositions, interrogatories, and document

[1] The record should clearly reflect that the United States is not identifying any targets of its criminal investigation, nor making any disclosure of grand jury materials or information. This declaration refers only to information in the public domain.

production requests, to seek information about and from persons who may be witnesses in the criminal investigation, some or all of whom may have been subpoenaed to appear before a federal grand jury. All of this information represents discovery to which Dr. Elamir, and others, would not be entitled under the Federal Rules of Criminal Procedure.

6. The disclosure of the identity of government witnesses and the substance of their statements to potential targets or subjects of an ongoing criminal investigation raises the prospect that Dr. Elamir will take advantage of the civil discovery provisions available in this proceeding and thereby harm the government's criminal case.

7. Therefore, continuation of this proceeding at this time may inure to the detriment of the criminal investigation being conducted by this Office. It may also insure to the detriment of any Grand Jury investigation that might be conducted, as well as any resultant criminal prosecution. In order to prevent such potential irreparable harm, the United States submits this affidavit in support of the NRC staff's response to the Licensing Board's Order of October 23, 1997, asking the NRC staff to provide information in support of Dr. Elamir's stay request. At the present time it appears that such a stay should be for no less than one hundred and twenty days, subject to the possibility of a request for an extension.

8. Pursuant to 18 U. S.C. Section 1746, 1 declare under penalty of perjury that the

foregoing is true and correct to the best of my knowledge, information and belief.

DATE: November 5, 1997

Bruce A. Levy
Assistant U.S. Attorney
District of New Jersey

Sworn to and subscribed before
me this 5th of November, 1997.

NOTARY PUBLIC

KATHLEEN M. BRICKLEY
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires April 27, 2001

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 15, 1997

Docket No. IA 97-068 Board Notification 97-02

MEMORANDUM TO: Atomic Safety and Licensing Board
and All Parties

FROM: Josephine M. Piccone, Chief
Operations Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: INFORMATION POTENTIALLY RELEVANT TO LICENSING BOARD PROCEEDING IN THE MATTER OF AHARON BEN-HAIM, PH.D.

In conformance with the Commission's policy on Board notifications, this memorandum calls attention to the agency's NRC Inspection Report No. 030-34086/97-001 dated September 5, 1997. This inspection report documents the NRC's findings at Newark Medical Associates, P.A., the licensee for which Dr. Ben-Haim performed consulting services. The findings in this inspection report are potentially relevant to a proceeding associated with an Order Superseding Order Prohibiting Involvement in NRC-Licensed Activities that was issued to Dr. Ben-Haim on August 27, 1997. A copy of the Order was provided to the Atomic Safety and Licensing Board on August 27, 1997. A copy of the September 5, 1997 inspection report is attached.

Attachment: NRC Inspection Report No. 030-34086/97-001 dated September 5, 1997

cc: Attached Service List

Charles Bechhoefer, Chairman
Administrative Judge
Atomic Safety and Licensing Board
Mail Stop T 3-F-23
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dr. Peter S. Lam
Atomic Safety and Licensing Board
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Office of the Commission Appellate
Adjudication
Mail Stop: 16-G-15 OWFN
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Office of the Secretary
ATTN: Rulemaking and Adjudications Staff
Mail Stop: 16-G-15
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Aharon Ben-Haim, Ph.D.*
3 Cloverhill Place
Montclair, NJ 07042

Adjudicatory File (2)
Atomic Safety and Licensing Board
Mail Stop: T-3F23
U.S. Nuclear Regulatory Commission
Washington, DC 2055

Atomic Safety and Licensing Board
Panel
Mail Stop: T-3F23
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Dr. Jerry R. Kline
Atomic Safety and Licensing Board
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U.S. Nuclear Regulatory Commission
Washington, DC 20555

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 5, 1997

Docket No. 030-34086 License No. 29-30282-01

Magdy Elamir, M.D.
President
Newark Medical Associates, P.A.
810 Broad Street
Newark, New Jersey 07102

SUBJECT: INSPECTION NO. 030-34086/97-001

Dear Dr. Elamir:

On January 29, February 6 and 7, and June 21, 1997, Richard Gibson of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. In addition, our inspection examined the activities covered in your correspondence dated February 6, 1997. The inspection was discussed with you by telephone on February 6, 1997, and with Dr. Maurizi by telephone on July 3, 1997.

Report No. 030-34086/97-001 documenting the results of that inspection is enclosed. The information in this report forms part of the basis for the recent Orders and Demand for Information issued to Newark Medical Associates and specific individuals. While this is not the final enforcement action for these matters, you should review the report and take specific actions to correct the identified apparent violations and to prevent recurrence prior to resuming any activities with licensed materials. We are considering whether additional enforcement action is appropriate for the apparent violations identified during this inspection. We will inform you of our conclusions in separate correspondence.

In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosed report will be placed in the Public Document Room (PDR). No response to this letter is necessary at this time. You must respond as required by existing Orders and the Demand for information. If you choose to provide us with any additional information, to the extent possible, you should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Your cooperation with us is appreciated.

Sincerely,

A. Randolph Blough, Director
Division of Nuclear Materials Safety

Docket No.: 030-34086
License No.: 29-30282-01
EA No.: 97-308
IA Nos.: 97-064, 97-065, 97-068

Enclosure:
Inspection Report No. 030-34086/97-001

cc w/enclosure:
R. Maurizi, M.D., Radiation Safety Officer
Aharon Ben-Haim, Ph.D.

Thomas H. Lee, II
Dechert Price & Rhoads
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Everett van Kampen
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State of New Jersey

Distribution: w/encl
PUBLIC
Nuclear Safety Information Center (NSIC)
Region I Docket Room (w/concurrences)
D. Holody, RI
J. Lieberman, OE
A. Hodgden, OGC

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-34086/97-001 Program Code 02200

Docket No. 030-34086

License No. 29-30282-01 Priority 3 Category G

Licensee: Newark Medical Associates, P.A.
810 Broad Street
Newark, New Jersey 07102

Facility Name: Newark Medical Associates, P.A.

Inspection At: 810 Broad Street
Newark, New Jersey

Inspection Conducted: January 29, February 6, 7, and June 21, 1997

Inspector: Richard Gibson, Jr. 9/4/97
Richard Gibson, Jr. date
Health Physicist

Approved By: John D. Kinneman 9.5.97
John D. Kinneman, Chief date
Nuclear Material Safety Branch 2
Division of Nuclear Materials Safety

Inspection Summary: Routine, announced safety inspection conducted on January 29, February 6, 7, and June 21, 1997 (Inspection Report No. 030-34086/97-001).

Areas Inspected: Organization; Scope of Licensed Activities; Personnel Monitoring; Facilities and Equipment; Surveys and Contamination Control; and Posting.

Results:

Within the scope of this inspection seven (7) apparent violations were identified:

1. Failure to provide complete and accurate information to the Commission (Section 2).

2. Failure to appoint a Radiation Safety Officer to implement the radiation safety program (Section 2).

3. Use of licensed material without an authorized user (Section 2).

4. Failure to provide personnel monitoring devices to individuals who are exposed to, and handle radiopharmaceuticals (Section 4).

5. Failure to monitor the external surfaces of a labeled package containing radioactive material (Section 6).

6. Failure to survey areas where radioactive waste is stored and where radiopharmaceuticals are routinely stored, prepared for use or administered (Section 6).

7. Failure to post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures, or post a notice describing these documents and where they may be examined (Section 7).

DETAILS

1. Persons Contacted

* Aharon Ben-Haim, Ph.D., Medical Physicist (Consultant)
* Lubika Smolokova, Magnetic Resonance Imaging Technician, Newark Medical Associates, P.A.
# Magdy Elamir, M.D., President and Owner, Newark Medical Associates, P.A.
# Gerard W. Moskowitz, M.D., Director, Division of Nuclear Medicine, University of Medicine and Dentistry of New Jersey, Newark, New Jersey
# Marina Geylikman, Nuclear Medicine Technologist, Harlem Hospital, New York, New York
# Romolo Maurizi, M.D., Pavonia Medical Associates, Jersey City, New Jersey

*Denotes attendance at exit interview
#Denotes contact by telephone

2. Organization

The application for NRC byproduct material License No. 29-30282-01 was signed by Magdy Elamir, M.D., President of Newark Medical Associates, P.A. (NMA). The only authorized user and the RSO named on the license when it was issued was Gerard W. Moskowitz, M.D. During the inspection, the inspector was informed that Aharon Ben-Haim, Ph.D. was a consultant to the licensee. The license was originally issued on September 25, 1996, and is due to expire on September 30, 2001.

During a telephone conversation with Magdy Elamir, M.D. on or about January 22, 1997, the inspector notified Dr. Elamir that the initial NRC safety inspection of NMA would be conducted on January 29, 1997. The inspector requested of Dr. Elamir that he and/or the Radiation Safety Officer (RSO) and only authorized user, Gerard W. Moskowitz, M.D., be present during the inspection. Dr. Elamir agreed that Dr. Moskowitz would be present for the inspection. When the inspector arrived at the facility on January 29, 1997, only Dr. Aharon Ben-Haim, the licensee's consultant was present. Dr. Ben-Haim stated that licensed materials were only used on Saturdays and that a Nuclear Medicine Technologist (NMT) comes from Harlem Hospital in New York to administer the material to the patient and perform the scans.

During a telephone conversation on February 6, 1997, Dr. Moskowitz stated to the inspector that he was not aware that he had been nor had he consented to being named as the RSO or the authorized user for NMA. In addition, he stated that he had never visited nor was he in any way involved in NMA activities. Dr. Moskowitz stated that he is employed full-time as the Director, Division of Nuclear Medicine at the University of Medicine and Dentistry of New Jersey (UMDNJ).

A Confirmatory Action Letter (CAL No. 1-97-004), was issued on February 6, 1997 to Newark Medical Associates, P.A., documenting NMA's agreement to immediately discontinue activities with byproduct material until such time as an amendment is filed and granted naming an RSO and authorized user. On February 7, 1997, the licensee faxed a letter dated February 6, 1997 requesting that the license be amended to name Romolo Maurizi, M.D., (authorized user at Pavonia Medical Associates in Jersey City, New Jersey, NRC License No. 29-30032-01) as the RSO and authorized user. The inspector contacted Dr. Maurizi on February 7, 1997. Dr. Maurizi stated that he was aware that he was to be named as RSO and authorized user on License No. 29-30282-01 for NMA, and that he would perform the duties of both positions required by NRC under the license. The license was amended to name Dr. Maurizi as the RSO and authorized user on February 7, 1997.

10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects. Submitting a name to the Commission to be listed on the license as the RSO and authorized user without the knowledge and consent of the individual is an apparent violation of 10 CFR 30.9(a).

10 CFR 35.21(a) requires that the licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. Failure to appoint a Radiation Safety Officer to implement the radiation safety program is an apparent violation of 10 CFR 35.21(a).

Condition 13 of License No. 29-30282-01 lists authorized users and states that licensed material is only authorized for use by, or under the supervision of, the individuals listed. From September 26, 1996 until February 6, 1997, Gerard W. Moskowitz, M.D. was the only authorized user listed on License No. 29-30282-01. Use of licensed material without an authorized user is an apparent violation of Condition 13 of License No. 29-30282-01.

3. Scope of Licensed Activities

The licensee is authorized to possess and use any radiopharmaceutical identified in 10 CFR 35.200 for any imaging and localization procedure approved in 10 CFR 35.200. Records of patient doses indicated that technetium-99m MDP is the only radiopharmaceutical used by the licensee. The licensee conducts imaging procedures only on Saturdays. Two to four patients are scanned each Saturday. According to licensee records, the NMA began aministering licensed material to patients on October 19, 1996. As of January 25, 1997, eleven patients had recieved licensed material. The patients are administered approximately 25 millicuries of technetium-99m MDP by a Nuclear Medicine Technologist (NMT).

The licensee also possesses and uses sealed sources (e.g. a cesium-137 vial, containing 247 microcuries; a cobalt-57 vial, containing 5.62 millicuries; and a

cobalt-57 flood source, containing 10 millicuries) for required calibration checks of the dose calibrator and for gamma camera quality control.

In addition to bone imaging, the licensee also conducts Magnetic Resonance Imaging (MRI) at the facility. MRI is an activity not regulated by the NRC at the facility.

No violations or safety significant items were identified.

4. Personnel Monitoring

On January 29, 1997, the inspector observed two (2) personnel monitoring badges. The badges were supplied by Landauer, Inc., and were dated February 5, 1997. The badges are scheduled to be exchanged on a monthly frequency. One of the badges was issued to the Nuclear Medicine Technologist (NMT), and the other was a control badge. Ring badges were not available at the time of the inspection. During a telephone conversation between the NMT and the inspector on February 6, 1997, the NMT stated that personnel monitoring devices had not initially been available for use at NMA. Instead the NMT used a badge provided by another employer (Harlem Hospital) while conducting imaging procedures at the licensee's facility. The NMT confirmed that the badges observed by the inspector were the first supplied by NMA.

Condition 16 of License No. 29-30282-01 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated February 21, 1996.

Item 9.4 of the application dated February 21, 1996 states that the licensee will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2. Appendix D states that all individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis. Appendix D also states that all individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

Failure to provide personnel monitoring devices (badges and rings) to all individuals who, on a regular basis, are occupationally exposed to, and handle radioactive material is an apparent violation of Condition 16 of License No. 29-30282-01.

5. Facilities and Equipment

The licensee is authorized to use byproduct material at 810 Broad Street, Newark, New Jersey. Bone imaging procedures are conducted in the scanning room which is adjacent to the hot laboratory on the 2nd floor of the facility. The

licensee possesses two survey instruments: a Ludlum Model 3, S/N 100682 and a Ludlum Model 5, S/N 128172, which were calibrated by Ludlum, Inc., on March 6, 1996 and September 16, 1996 respectively; a dose calibrator, Victoreen Model 34-056, S/N 14978; an L-shield with lead bricks; and several check sources for calibrating the dose calibrator. The required calibration checks of the dose calibrator were conducted by the licensee's consultant, Aharon Ben-Haim, Ph.D. The inspector determined that the dose calibrator was calibrated as required.

No violations or safety significant items were identified.

6. Surveys and Contamination Control

On January 29, 1997, records of package receipt including records of package radiation level surveys were reviewed. The inspector determined that the licensee is performing radiation level surveys at the package surface and at one meter from the package. However, records of surveys for removable radioactive contamination on the external surfaces of labeled packages were not available at the time of the inspection. In addition, records of surveys for removable contamination and radiation levels in all areas where radiopharmaceuticals are routinely prepared for use, administered and stored were also not available during the inspection. The consultant, Dr. Ben-Haim, stated that these surveys were not performed.

10 CFR 20.1906(b) requires, in part, that each licensee monitor the external surfaces of a package labeled with a Radioactive White 1, Yellow II, or Yellow III label for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4. Failure to monitor the external surfaces of a labeled package for radioactive contamination is an apparent violation of 10 CFR 20.1906(b).

10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste are stored. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored. Failure to perform required daily and weekly surveys with a radiation detection survey instrument and weekly surveys for removable contamination in all areas where radiopharmaceutical waste is stored and where radiopharmaceuticals are routinely prepared for use, administered and stored at the required frequency is an apparent violation of 10 CFR 35.70(a), (b) and (e).

7. Posting

Form NRC-3 "Notice to Employees", and other required documents were not posted nor were these forms and documents available for review at the time of the inspection.

10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees." Failure to post Form NRC-3, "Notice to Employees", current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, or post a notice describing these documents and where they can be examined is an apparent violation of 10 CFR 19.11(a), (b) and (c).

8. Exit Interview

The inspector met with the licensee's consultant Aharon Ben-Haim, Ph.D. on January 29, 1997; and with Magdy Elamir, M.D. by telephone on February 6, 1997 to discuss the purpose, scope and findings of the inspection and NRC enforcement policy.

9. June 21, 1997 Visit

The inspector visited NMA on Saturday, June 21, 1997 to observe licensed activities. The MRI Technician, Lubika Smolokova stated that only one patient had been scheduled for a bone scan that day, and that that patient had been postponed by the licensee to the following Saturday, June 28, 1997. She stated that the licensee does not request that the NMT come from New York for just one bone scan and that is why the patient was instructed to come for the scan the following Saturday. Ms. Smolokova then refused to continue with additional questions regarding activities with licensed material.

10. Discussion with Dr. Maurizi

On July 3, 1997, Dr. Maurizi was contacted by the Acting Chief, Nuclear Materials Safety Branch No. 2 to determine his current involvement in NMA's radiation safety program and to review the inspection results. Dr. Maurizi stated that he is "not really there," that scans are sent to him to read and that NMA has only done a few patients since he was named as the authorized user and RSO on the license. He stated that he had been to the facility "a couple of times" before they started to perform scans on patients under his supervision to look at the hot laboratory and camera equipment. He stated that he had not met any of the nuclear medicine technologists. He stated that he had not instructed the nuclear medicine technologists in the principles of radiation safety appropriate to the use

of radioactive materials at the facility, but that the physicist (Dr. Ben-Haim) may have done such training. Dr. Maurizi was informed of the apparent violations identified during the inspection and that, as the individual responsible for the radiation safety program at NMA, he must ensure that timely corrective actions are taken.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	
	)	
MAGDY ELAMIR, M.D.	)	IA-97-070
	)	
Newark, New Jersey	)	

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF RESPONSE TO LICENSING BOARD ORDER" and Board Notification in the above-captioned proceeding have been served on the following through deposit in the Nuclear Regulatory Commission's internal mail system, or by deposit in the United States mail, first class, as indicated by an asterisk this 14th day of November, 1997:

Charles Bechhoefer, Chairman
Administrative Judge
Atomic Safety and Licensing Board
Mail Stop T 3-F-23
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dr. Jerry R. Kline
Atomic Safety and Licensing Board
Mail Stop T 3-F-23
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dr. Peter S. Lam
Atomic Safety and Licensing Board
Mail Stop: T-3F23
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Adjudicatory File (2)
Atomic Safety and Licensing Board
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Office of the Commission Appellate Adjudication
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Washington, DC 20555

Office of the Secretary (2)
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Dechert Price & Rhoads
4000 Bell Atlantic Tower
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