



SECRETARY

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

October 9, 1997

DOCKET NUMBER
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IA 97-070

DOCKETED
USNRC

97 OCT 15 P3:58

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

MEMORANDUM TO: B. Paul Cotter, Jr.
Chief Administrative Judge
Atomic Safety and Licensing Board Panel

FROM: *John C. Hoyle*
John C. Hoyle, Secretary

SUBJECT: ANSWER AND REQUEST FOR HEARING
SUBMITTED BY DR. MAGDY ELAMIR

Attached is an answer and hearing request submitted by Dr. Magdy Elamir (IA 97-070), President of Newark Medical Associates, P.A. (NMA). The answer and hearing request were submitted in response to an "Order Superseding Order Prohibiting Involvement in NRC Licensed Activities (Effective Immediately)" issued by the NRC Staff on September 15, 1997. The Order was published in the Federal Register at 62 Fed. Reg. 49536 (September 22, 1997) (Copy Attached).

Dr. Elamir as well as NMA (see attached answer of NMA to staff demand for information and request for stay) have requested a stay of all proceedings concerning this matter pending a response by the Department of Justice to a referral by the staff.

The answer and request for hearing, as well as, the stay requests of Dr. Elamir and NMA are being referred to you for appropriate action in accordance with 10 C.F.R. Sec. 2.772(j).

Attachments: as stated

cc: Commission Legal Assistants
OGC
CAA
OPA
EDO
NMSS
OE
Thomas H. Lee
Rachel Nosowsky
Dechert Price & Rhoads
Perry D. Robinson
Winston & Strawn

18576

LAW OFFICES OF

DECHERT PRICE & RHOADS

DOCKETED
USNRC

1500 K STREET, N.W.
WASHINGTON, DC 20005-1208
(202) 626-3300

30 ROCKEFELLER PLAZA
NEW YORK, NY 10112
(212) 698-3500

PRINCETON PIKE CORPORATE CENTER
P.O. BOX 5218
PRINCETON, NJ 08543-5218
(609) 520-3200

THIRTY NORTH THIRD STREET
HARRISBURG, PA 17101-1603
(717) 237-2000

TEN POST OFFICE SQUARE SOUTH
BOSTON, MA 02109-4603
(617) 728-7100

90 STATE HOUSE SQUARE
HARTFORD, CT 06103-3702
(860) 524-3999

4000 BELL ATLANTIC TOWER
1717 ARCH STREET
PHILADELPHIA, PA 19103-2793

TELEPHONE: (215) 994-4000
FAX: (215) 994-2222

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS

65 AVENUE LOUISE
1050 BRUSSELS, BELGIUM
(32-2) 535-5411

TITMUS SAINER DECHERT
2 SERJEANTS' INN
LONDON EC4Y 1LT, ENGLAND
(44-171) 583-5353

151, BOULEVARD HAUSSMANN
75008 PARIS, FRANCE
(33-1) 53 83 84 70

Direct Dial: (215) 994-2649
rnosowsk@dechert.com

October 4, 1997

VIA FEDERAL EXPRESS

Secretary
U.S. Nuclear Regulatory Commission
16th Floor, One White Flint North
11555 Rockville Pike
Rockville, MD 20852
ATTN: Chief, Rulemaking and Adjudications

Re: Magdy Elamir, M.D., IA 97-064; IA 97-070; Newark
Medical Associates, EA 97-308

To whom it may concern::

Pursuant to the Commission's July 31, 1997 Demand for Information and September 15, 1997 Order Superseding Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately), please find originals (except as specified) of the following documents:

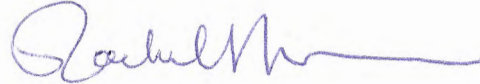
- Answer of Dr. Magdy Elamir to the Superseding Order (with Demand for Hearing and Request for Stay of All Proceedings and notarized Verification);
- Answer of Newark Medical Associates, P.A. to the Demand for Information (with Request for Stay of All Proceedings and notarized Verification) (copy only; original to the Director, Office of Enforcement;
- Entry of Appearance of Thomas H. Lee, II, Esquire and Rachel Nosowsky, Esquire, Dechert Price & Rhoads, on behalf of Newark Medical Associates and Magdy Elamir;
- Entry of Appearance of Perry D. Robinson, Esquire, Winston & Strawn, on behalf of Newark Medical Associates and Magdy Elamir;

Secretary
October 4, 1997
Page 2

Certificate of Service

If you have any questions about the enclosed documents, please do not hesitate to call Tom Lee (215/994-2994) or me (215/994-2649) at your convenience.

Respectfully,



Rachel Nosowsky

RN/rmp
Enclosures

cc: Director, Office of Enforcement (by FedEx; w/ enclosures)
Assistant General Counsel for Hearings and Enforcement (by FedEx; w/ enclosures)
Regional Administrator, Region I (by FedEx; w/ enclosures)
Docketing Service Branch, Rockville, MD (by FedEx; w/ enclosures)

DOCKETED
USNRC

UNITED STATES
NUCLEAR REGULATORY COMMISSION '97 OCT -6 P5:23

In the Matter of

MAGDY ELAMIR, M.D.
Newark, New Jersey

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:
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IA 97-064
IA 97-070

OFFICE OF SECRETARY
RULEMAKING AND
ADJUDICATIONS STAFF

ANSWER OF DR. MAGDY ELAMIR TO THE COMMISSION'S
SEPTEMBER 15, 1997 ORDER SUPERSEDING ORDER
PROHIBITING INVOLVEMENT IN NRC-LICENSED ACTIVITIES

Respondent Magdy Elamir, M.D., pursuant to 10 C.F.R. § 2.202(b), hereby responds to the Order Superseding Order Prohibiting Involvement in NRC-Licensed Activities (the "Superseding Order") by denying that he ever deliberately caused Newark Medical Associates ("NMA") to violate any law or regulation imposed by the Nuclear Regulatory Commission ("NRC" or "Commission") or any restriction imposed by Byproduct Nuclear Material License No. 29-30282-01. A more specific response to the allegations contained in the Superseding Order is set forth below.

I.

Magdy Elamir, M.D. (Dr. Elamir), is the Owner/President of Newark Medical Associates, P.A. (licensee). The licensee holds Byproduct Nuclear Material License No. 29-30282-01 (license) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The license authorizes possession and use of any radiopharmaceutical identified in 10 CFR 35.200 for any imaging and localization procedure approved in 10 CFR 35.200. The license was originally issued on September 25, 1996, and is due to expire on September 30, 2001.

Admitted.

II.

During a new license inspection conducted on January 29, 1997 at the licensee's facility, several apparent violations of NRC requirements were identified. Subsequent to the inspection, the NRC initiated an investigation which led the NRC to issue to Dr. Elamir, on July 31, 1997, an Order Prohibiting Involvement in NRC Licensed Activities (Effective Immediately) Pending Further Order (62 Fed. Reg. 43360). That Order was issued pending completion of NRC staff review of the results of the investigation, which was conducted by the NRC's Office of Investigations (OI). The NRC staff's review of the results of the OI investigation is now complete.

It is admitted that the NRC conducted a new license inspection on January 29, 1997 at NMA. It is further admitted that the NRC then initiated an investigation and that an Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) was issued on July 31, 1997. However, to the extent that Part II of the Superseding Order implies that the NRC's conclusions and actions are supported by applicable law and facts, this allegation is denied. Dr. Elamir has insufficient knowledge or information to form a belief as to the truth of the remaining allegations of Part II of the Superseding Order and therefore denies them.

III.

The OI Investigation focused, in part, on Dr. Elamir's actions in causing the licensee to be in violation of NRC requirements. The NRC learned during the investigation that Dr. Elamir transmitted an inaccurate license application (NRC Form 313, dated February 21, 1996) to the NRC. The license application named Newark Medical Associates as the prospective licensee. The license application was inaccurate in that it named Gerard W. Moskowitz, M.D. (Dr. Moskowitz) as the only authorized user and Radiation Safety Officer (RSO) without Dr. Moskowitz's consent or knowledge, and without Dr. Moskowitz's ever having been affiliated or associated with the licensee. Dr. Moskowitz did not ever perform the role of authorized user or RSO at the licensee's facility and did not become aware that he was listed on the application and the license until notified by the NRC on February 6, 1997, more than four months after the license was originally issued. These inaccurate statements in the license application submitted by Dr. Elamir, formed, in part, the basis for the issuance of the license to Newark Medical Associates on September 25, 1996.

On October 17, 1996, Dr. Elamir notified the NRC by letter that Newark Medical Associates was initiating activities authorized by the license: and during the period from November 1996 through February 6, 1997, Dr. Elamir, in his capacity as president and owner of Newark Medical Associates, caused and permitted the licensee to conduct NRC-licensed activities even though he knew that the licensee did not employ the authorized user or the RSO named in the license application and, subsequently, on the NRC license, and that the named individual did not serve in these capacities. Based on the results of the OI investigation, the NRC has determined that Dr. Elamir's actions constitute violations of the Commission's requirements as follows:

- A. 10 CFR 30.10(a)(2) requires, in part, that any licensee or employee of a licensee may not deliberately submit to the NRC information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.**

During a February 6, 1997 telephone conversation between Dr. Elamir and an NRC inspector, Dr. Elamir stated to the NRC inspector that the Newark Medical Associates license was current with respect to the authorized user and RSO even though Dr. Elamir knew that the individual named on the license as the authorized user and RSO was not performing those duties and was not ever affiliated with the licensee in any capacity. This inaccurate statement was material because it had the ability to influence an NRC inspection.

- B. 10 CFR 30.10(a)(1), (c)(1), and (c)(2) require, in part, that any licensee or employee of a licensee not engage in deliberate misconduct that causes or, but for detection, would have caused a licensee to be in violation of: (1) any rule, regulation, or order, or any term, condition, or limitation of any license issued by the Commission; or (2) any requirement, procedure, instruction, contract, purchase order, or policy of a licensee.**

- 1. 10 CFR 35.21 requires that a licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program; and requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.**

10 CFR 35.13 requires that a licensee apply for and receive a license amendment before it changes Radiation Safety Officers.

Byproduct Material License No. 29-30282-01, Condition 12, dated September 25, 1996 states that the Radiation Safety Officer for this License is Gerard W. Moskowitz, M.D.

On October 17, 1996, Dr. Elamir notified the NRC by letter that Newark Medical Associates was initiating activities authorized by the license; and, during the period from November 1996 through February 6, 1997, Dr. Elamir caused Newark Medical Associates to be in violation of the requirements of Section III.B.1 above by deliberately causing and permitting the licensee to conduct licensed activities even though Dr. Elamir knew that the individual designated as the RSO on the Newark Medical Associates license application and subsequent license did not ever serve as the Radiation Safety Officer under that license and was not ever affiliated with the licensee in any capacity.

- 2. 10 CFR 35.11(a) and (b) permit an individual to use licensed material for medical use only in accordance with a specific license issued by the Commission or under the supervision of an authorized user as provided in 10 CFR 35.25.**

Byproduct Material License N. 29-30282-01, dated September 25, 1996, states in Condition 13 that licensed material is only authorized for use by, or under the supervision of, Gerard W. Moskowitz, M.D.

On October 17, 1996, Dr. Elamir notified the NRC by letter that Newark Medical Associates was initiating activities authorized by the license; and during the period from November 1996 through February 6, 1997, Dr. Elamir caused Newark Medical Associates to be in violation of the requirements in Section III.B.2 above by deliberately causing and permitting licensed activities to be conducted by a technologist who did not hold a specific license issued by the NRC and who was not under the supervision of the authorized user specified on the license. Dr. Elamir knew that the individual designated as the only authorized user on the Newark Medical Associates license application and subsequent license did not ever serve as the authorized user under that license and was not ever affiliated with the licensee in any capacity.

Insofar as Part III alleges that Dr. Elamir deliberately submitted to the NRC information that he knew to be incomplete or inaccurate in some respect material to the NRC, or that he engaged in deliberate misconduct, these allegations are denied.

In February 1996, Dr. Elamir retained Dr. Aharon Ben-Haim, a physicist whom he understood to be an expert in NRC regulations and licensing, as a consultant. Dr. Ben-Haim was to assist NMA in obtaining an NRC license, maintaining and operating equipment used in medical procedures subject to NRC regulation, training and supervising staff in performing those procedures, and ensuring compliance with NRC regulations (Exhibits A and B). In performing his contractual obligation to prepare NMA's state and federal license applications, Dr. Ben-Haim informed Dr. Elamir that NMA would need a qualified individual to serve as Radiation Safety Officer and authorized user.

In February 1996, Dr. Elamir's office was negotiating a professional radiology services agreement (Exhibit C) with the University of Medicine and Dentistry/New Jersey ("UMDNJ"). Under the proposed agreement, UMDNJ would have read and interpreted MRI and other radiology images for imaging centers owned by Dr. Elamir, including NMA. During discussions in or about February 1996, Dr. Stephen Baker, Chairman of the Department of Radiology at UMDNJ, suggested to Dr. Elamir that Dr. Moskowitz could serve as NMA's RSO and provided Dr. Moskowitz's phone number to Dr. Elamir. Dr. Elamir relayed this information to Dr. Ben-Haim and requested that Dr. Ben-Haim contact Dr. Moskowitz about becoming NMA's RSO and authorized user and to obtain the information on Dr. Moskowitz's qualifications which Dr. Ben-Haim had informed Dr. Elamir would be required as part of NMA's license applications. Dr. Ben-Haim later told Dr. Elamir that he had met with Dr. Moskowitz, had obtained from Dr. Moskowitz the documents necessary to complete NMA's license applications, and that everything was in order. Dr. Elamir understood from this and his earlier

conversation with Dr. Baker that Dr. Moskowitz was ready and willing to serve as NMA's RSO and authorized user. Dr. Ben-Haim subsequently prepared the NRC application which Dr. Elamir signed at Dr. Ben Haim's direction. Thus, at the time he signed the NRC license application, Dr. Elamir believed that all of the information in the application, including the designation of Dr. Moskowitz as NMA's RSO and authorized user, was accurate and correct.

On or about October 17, 1996, pursuant to Dr. Ben-Haim's explicit instructions, Dr. Elamir wrote to the NRC to inform the Commission that NMA planned to initiate activities authorized by its license. Dr. Elamir believed, based on his discussions with Dr. Ben-Haim, that the information contained in the letter was true and correct. Between October 1996 when the letter was written and February 6, 1997, Dr. Ben-Haim represented to Dr. Elamir that Dr. Ben-Haim and his staff were authorized, through a delegation of authority from Dr. Moskowitz, to engage in NRC-licensed activities. When Dr. Elamir first learned on February 6, 1997 that Dr. Moskowitz had apparently not properly delegated his authority as RSO and authorized user to Dr. Ben-Haim, Dr. Elamir promptly caused NMA to apply to the Commission for an amended license to replace Dr. Moskowitz as RSO and authorized user with Dr. Romolo Maurizi. The Commission issued an amended license on February 7, 1997 naming Dr. Maurizi NMA's RSO and authorized user.

It is admitted that, during a telephone conversation on or about February 6, 1997, Dr. Elamir told an NRC inspector that the NMA license was current with respect to the RSO and authorized user. At the time he made this statement, Dr. Elamir believed it to be true and correct. Specifically, Dr. Elamir believed that Dr. Moskowitz was NMA's RSO and authorized user. Dr.

Elamir's representations to the NRC inspector were made in reliance on Dr. Ben-Haim's superior knowledge of NRC regulations, Dr. Ben-Haim's general expertise as a physicist, and Dr. Ben-Haim's representations about his meeting with Dr. Moskowitz and the delegation of authority from Dr. Moskowitz through Dr. Ben-Haim to the technicians responsible for performing NRC-regulated procedures at NMA.

To the extent that Part III contains allegations summarizing portions of Title 10 of the Code of Federal Regulations, these allegations are denied as stated; the regulations speak for themselves. Dr. Elamir has insufficient knowledge or information to form a belief as to the truth of the allegations concerning what the NRC "learned" or when, and therefore denies them. To the extent that any remaining allegations in Part III remain unanswered, they are denied.

Based on the above, the NRC staff has concluded that Dr. Elamir deliberately caused the licensee to be in violation of NRC requirements by causing and permitting the licensee to conduct licensed activities in the absence of the authorized user and RSO named on the license application and on the NRC license. The NRC must be able to rely on the licensee and its employees to comply with NRC requirements. Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public, including patients receiving radiation from byproduct material for medical purposes, will be protected if Dr. Elamir were permitted at this time to be involved in NRC-licensed activities. Therefore, the public health, safety, and interest require that Dr. Elamir be prohibited from any involvement in NRC-licensed activities for a period of five years. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of Dr. Elamir's conduct described above is such that the public health, safety, and interest require that this Order be immediately effective.

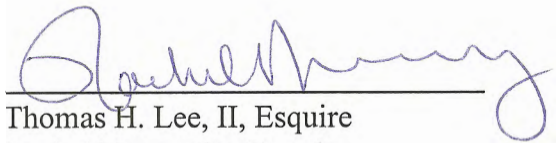
Dr. Elamir denies that he ever deliberately caused NMA to violate NRC requirements. To the contrary, at all relevant times Dr. Elamir acted in the belief that Dr. Ben-Haim was authorized to perform the functions of RSO and authorized user at NMA by delegation

of authority from Dr. Moskowitz and, more generally, that under Dr. Ben-Haim's direction, NMA activities were being conducted in full compliance with NRC requirements.

Insofar as the NRC has concluded that the public health, safety, and interest require that Dr. Elamir be prohibited from any involvement in NRC-licensed activities for a period of five years, this conclusion is rejected as unsupported by the evidence or relevant legal precedent. The Commission has not met its burden, set forth at 10 C.F.R. § 2.732, to demonstrate that the Superseding Order is factually or legally supported.

WHEREFORE, the Superseding Order should be set aside or modified consistent with the facts of this case and a hearing is demanded, as set forth in the attached Demand for Hearing, to fully and fairly adjudicate this matter.

Respectfully,

A handwritten signature in blue ink, appearing to read "Thomas H. Lee, II", is written over a horizontal line.

Thomas H. Lee, II, Esquire
~~Rachel Nosowsky, Esquire~~
DECHERT PRICE & RHOADS
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103
(215) 994-4000

Perry D. Robinson, Esquire
WINSTON & STRAWN
1400 L Street, NW
Washington, DC 20005-3502
(202) 371-5700

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

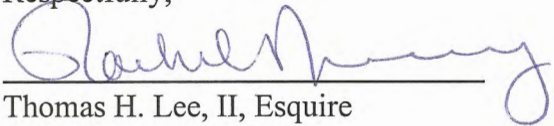
MAGDY ELAMIR, M.D.
Newark, New Jersey

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: IA 97-064
: IA 97-070
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DEMAND FOR HEARING AND
REQUEST FOR STAY OF ALL PROCEEDINGS

Pursuant to 10 C.F.R. § 2.202(b), Respondent Magdy Elamir, M.D., hereby demands a full and fair hearing before a duly appointed Atomic Safety and Licensing Board. In light of the fact, however, that this matter has been referred to the Department of Justice, Respondent requests that the hearing and all other proceedings in this matter be stayed pending resolution of the referral. Dr. Elamir is subject to an Order prohibiting his involvement in NRC-licensed activities, and Newark Medical Associates has agreed not to engage in any NRC-licensed activities pending resolution of these matters. Therefore, the granting of a stay will not prejudice the NRC.

Respectfully,



Thomas H. Lee, II, Esquire
Rachel Nosowsky, Esquire
DECHERT PRICE & RHOADS
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103
(215) 994-4000

Perry D. Robinson, Esquire
WINSTON & STRAWN
1400 L Street, NW
Washington, DC 20005-3502
(202) 371-5797

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

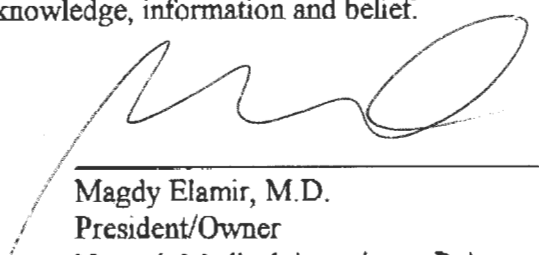
MAGDY ELAMIR, M.D.
Newark, New Jersey

IA 97-064
IA 97-070

VERIFICATION

I, Magdy Elamir, M.D., affirm that the statements set forth in the attached

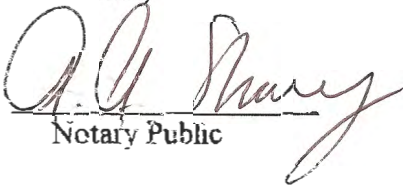
Answer are true and correct to the best of my knowledge, information and belief.



Magdy Elamir, M.D.
President/Owner
Newark Medical Associates, P.A.

Subscribed and sworn to
before me this 3rd day
of October, 1997.

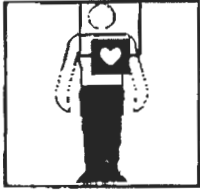
10 - 3 - 97
Date



Notary Public

ARTHIIS AMEEN SHAREEF
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES JULY 15, 1999

EXHIBIT A



Aharon Ben-Haim, Physicist
52 Watchung Avenue
Upper Montclair, NJ 07043
Tel: (201) 783-3638
Fax: (201) 783-8479
Pager: (800)906-2646

Dr. Magdy Elamir
Submitted in Person

February 15, 1996

PROPOSAL

We offer to obtain on your behalf in the shortest possible time your State and Federal Material Licenses. At the same time, we will install your Hot Laboratory and establish the necessary Radiation Health procedures. The Hot Lab will be equipped with the necessary Measurement and Calibration equipment and materials, Counters, Meters and Waste Containers. We will prepare for State and NRC inspections.

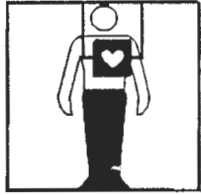
We will assure continuous monitoring of the Laboratory in compliance with the regulations of the Nuclear Regulatory Commission. We will train your staff, assist you in staffing requirements, perform all equipment tests, such as Dose Calibrator constancy, accuracy and linearity, assure that proper procedures are used in the handling of radioactive material, etc.

Sincerely yours,

A handwritten signature in cursive script, reading "Aharon Ben-Haim".

Dr. Aharon Ben-Haim

EXHIBIT B



Aharon Ben-Haim, Physicist
52 Watchung Avenue
Upper Montclair, NJ 07043
Tel: (201) 783-3638
Fax: (201) 783-8479
Pager: (800)906-2646

Dr. Magdy Elamir
Submitted in Person

February 20, 1996

QUOTATION/AGREEMENT

I am pleased to submit the following quotation:

1. For a comprehensive maintenance service contract for your Elscint 409 A SPECT Gamma Camera, including physicist services, yearly \$16,000.00, payable quarterly at the beginning of each quarter. As a physicist, I will supervise your staff in all aspects related to the safe use of radioisotopes.

2. For a Complete Refurbished Hot Laboratory Unit comprising:

1 Calibrated Dose Calibrator for syringes and multidose vials.

1 Calibrated Survey Meter for Area Surveys, provided with Timer/Scaler for dpm counting (Wipe Tests)..

1 Lead glass shielded Dose Preparation Station.

1 Pair of Ustensil Prongs.

2 Syringe shields.

1 Desk top shielded syringe container.

1 Large shielded Waste Container.

Total price: \$7,500.00.

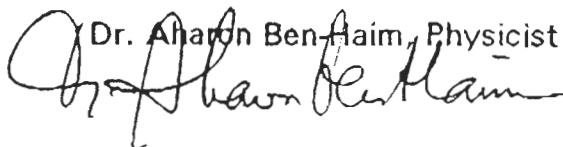
Terms: 50% Down with Purchase Order.
50% at Installation.

3. For preparation of State and NRC licenses: \$500.00. Due immediately.

By apposing your signature below on the right you are agreeing to my offer and its terms.

Sincerely yours,

For Newark Medical Associates

Dr. Aharon Ben-Haim, Physicist


Dr. Magdy Elamir


EXHIBIT C

MEDICAL SERVICES AGREEMENT

THIS AGREEMENT entered into this day of , 199
 , by and between the University of Medicine and Dentistry
 of New Jersey ("University") with offices at University
 Heights, Administration Complex #1, 30 Bergen Street,
 Newark, New Jersey 07107-3000 on behalf of the UMDNJ-New
 Jersey Medical School ("School") and Irvington MRI and
 Affiliated MRI Centers, with offices at
 , NJ ("Irvington").

WHEREAS, Irvington desires the services of experts in the
 delivery of radiology services;

WHEREAS, the School through its faculty in the Department
 of Radiology at the School possesses the expertise to
 provide the requisite services;

NOW THEREFORE, in consideration of the terms and
 conditions contained herein the parties hereto agree as
 follows:

radiology services:

- (a) interpretation of Irvington's magnetic resonance imaging studies and other radiology images for four (4) hours per day, Monday through Friday, excluding holidays and other days when School does not operate, subject to the following conditions:
- (b) that all magnetic resonance images shall be transported to School premises and returned to Irvington by Irvington at Irvington's expense. Reading and interpretation will be done by School on School premises.
- (c) that all other radiology images may either be transported to School premises and returned by Irvington at Irvington's expense or communicated by electronic means agreed upon by the parties. The cost of installation, maintenance and use of such electronic communication shall be borne equally by the parties.

(d) that all arrangements and expenses associated with the transcription and signing of radiology reports shall be the sole responsibility of Irvington.

(e) that School shall provide timely reports of interpretation results in writing or by electronic means, depending on the circumstances and the judgement of the radiologist.

2. Origination of Radiology Images Irvington and School agree that School shall not provide radiology services connected with images that are produced in Bayonne or Jersey City, New Jersey and that Irvington will not provide to School any images for interpretation that originated in those locations. School is contractually obligated to exclusive provision of radiology services in those locations to another party.

3. Term Services shall commence February 15, 1996 and shall continue to and shall be automatically renewed

annually thereafter, unless otherwise terminated pursuant to Section 7 herein or by mutual consent of the parties.

4. ~~Fee~~ Irvington agrees to pay the School according to the following schedule:

- (a) The cost to School of salary and fringe benefits of qualified radiologist's services to be provided pursuant to this agreement, which in the first year following execution shall be:

\$97,000.00 - base salary,

~~\$21,340.00 - fringe benefits~~

\$118,340.00 - total fee.

- (b) Fees and monthly payments by Irvington pursuant to this agreement shall be adjusted by School annually to reflect salary and fringe benefit adjustments of School.

- (c) For each contract year Irvington agrees to pay

to the School each month one-twelfth of the total fee pursuant to this section, payable no later than the 15th day of each month following first performance of services. Payment will be by check to the order of UMDNJ - New Jersey Medical School and mailed to: Department of Radiology, UMDNJ - New Jersey Medical School, 185 South Orange Avenue, Newark, NJ 07103-2714, Attn: Dr. Stephen Baker, Chair.

5. ~~Independent Contractor~~ The University shall remain an independent contractor for the term of this Agreement. Nothing contained herein shall be construed to make the University an employee or agent of the Irvington.

6. ~~Liability Coverage~~ Irvington shall be responsible throughout the duration of this Agreement and any renewals thereof, for maintaining a policy of insurance providing for professional and general liability insurance coverage of Irvington, its officers, employees, and agents and School and its employees who provide services pursuant to this agreement, subject to limits of coverage of not less than \$1,000,000/\$3,000,000. A

certificate of insurance shall be provided to the University naming the University as certificate holder and additional insured as its interests appear under this Agreement said insurance shall be deemed primary insurance.

The University shall provide for professional and general liability coverage insuring the University and its faculty, students and employees performing activities under this agreement through a Program of Self-Insurance providing limits of coverage of \$1,000,000/\$3,000,000 on an occurrence type basis pursuant to N.J.S.A. 59:1-1 et seq., the State of New Jersey Tort Claims Act. The University, upon request, shall furnish documentation certifying the funding mechanism of said Program.

7. Default In addition to any other rights in law or in equity, in the event that either party defaults in any term or condition of this Agreement, the non-defaulting party may terminate this Agreement upon 30 days written notice.

8. Termination University and Irvington shall have the right to terminate this Agreement upon Sixty (60) days

prior written notice without cause. In the event of any termination pursuant to this Agreement, University agrees to forward to Irvington all work performed as of the date of termination and Irvington agrees to immediate payment of all fees owed for work performed.

9. Non-Waiver The failure of either party to insist on strict performance of any of the provisions of this Agreement shall not be construed as a waiver of any other default whether or not of the same or similar nature.

10. Entire Agreement The parties agree that they are not relying upon any promises, understanding, warranties, circumstances, conduct, negotiations, expectations, representations or agreements, oral or written, express or implied, other than those expressly set forth herein; that this Agreement is complete integration and constitutes the entire agreement of the parties with respect to the subject matter hereof; that no amendments or other modifications of the Agreement shall be valid unless in writing and signed by an authorized officer of each party hereto; that this entire Agreement has been bargained for and negotiated; and the parties have read, understood and approved this Agreement in its entirety.

11. Governing Law This Agreement shall be governed by the laws of the State of New Jersey.

12. Notices to be sent pursuant to this Agreement shall be mailed, certified, as follows:

If to Irvington:

If to University:

Senior Vice President for
Administration & Finance
University of Medicine and
Dentistry of New Jersey
University Heights
65 Bergen Street,
Suite 1419
Newark, New Jersey 07107

With copies to:

Chairman
Department of Radiology
University of Medicine and
Dentistry of New Jersey
New Jersey Medical School
105 South Orange Avenue
Newark, New Jersey 07103

13. Non-Discrimination The provisions of Section 202 of Executive Order 11246 and Section 60-1.4. and 60-1.7, 60-1.8 of Chapter 60 of 41 Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of race, color, religion, sex or national origin; Section 60-741.4 of

Chapter 60 of 41 Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of physical or mental handicap; and Section 60-250.4 of Chapter 60 of 41 code of Federal Regulations, as amended, providing for the employment of disabled veterans and veterans of the Vietnam era, are hereby incorporated by reference to the same extent and with the same force and effect as it is set forth herein in full.

14. Non Collusion Both parties agree that no fee, commission, compensation gift or gratuity was paid or received regards to the solicitation of this Agreement, in contravention to N.J.S.A 52:13D-13 et seq.

IN WITNESS WHEREOF the parties hereto set their hand and seal the date first above written.

FOR Irvington

FOR UNIVERSITY OF MEDICINE
& DENTISTRY OF NEW JERSEY

Frederick J. Hammond, Jr.
Senior Vice President for
Administration & Finance

DATE

DATE

Recommended By:

Ruy Lourenco, M.D., Dean

DATE

DOCKETED
USNRC

UNITED STATES
NUCLEAR REGULATORY COMMISSION

97 OCT -6 P5:23

In the Matter of

NEWARK MEDICAL ASSOCIATES, P.A. :
Newark, New Jersey :

Docket No. 030-34086

License No. 29-30282-01

EA 97-308

OFFICE OF SECRETARY
RULEMAKING AND
ADJUDICATIONS STAFF

ANSWER OF NEWARK MEDICAL ASSOCIATES, P.A.
TO THE COMMISSION'S JULY 31, 1997
DEMAND FOR INFORMATION

Respondent, Newark Medical Associates, P.A. ("NMA"), pursuant to 10 C.F.R. § 2.204(b), hereby responds to the Demand for Information by denying that NMA ever knowingly violated any law or regulation imposed by the Nuclear Regulatory Commission ("NRC" or "Commission") or any restriction imposed by Byproduct Nuclear Material License No. 29-30282-01. A more specific response to the allegations contained in the Demand for Information is set forth below.

I.

Newark Medical Associates, P.A. (licensee) holds Byproduct Materials License No. 29-30282-01 (license), issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 C.F.R. Part 30. The license authorizes the licensee to possess and use any radiopharmaceutical identified in 10 C.F.R. 35.000 for any imaging and localization procedure approved in 10 C.F.R. 35.200. The license, originally issued on September 25, 1996, was amended on February 7, 1997, and is due to expire on September 30, 2001.

Admitted.

II.

On January 29, 1997, the NRC conducted an inspection at the licensee's facility in Newark, New Jersey. During the inspection, several apparent violations of NRC requirements were identified. One of the violations involved the continued use of radioactive material by the licensee despite the fact that the only authorized user listed on the license (who was also listed as the Radiation Safety Officer (RSO)), had not ever performed any authorized user or RSO duties and had not ever been affiliated with the company. Moreover, the licensee had not ever informed the NRC that that individual named in its license application was not acting as the authorized user and RSO. Specifically, Gerard W. Moskowitz, M.D. (Dr. Moskowitz), was listed on the application as the RSO and authorized user without his knowledge. Dr. Moskowitz did not become aware that he was listed on the application and the license until notified by the NRC on February 6, 1997, more than four months after the license was originally issued.

Subsequent to the inspection, the NRC verified, based on an investigation by the NRC Office of Investigations (OI), that the licensee's letter, dated February 22, 1996, transmitting the application (NRC Form 313), dated February 2, 1996, for a byproduct material license, was inaccurate in that it listed Dr. Moskowitz as the authorized user and Radiation Safety Officer without Dr. Moskowitz's consent or knowledge and without Dr. Moskowitz ever having been affiliated or associated with the licensee. Further, Dr. Moskowitz did not ever perform the role of RSO at the facility. As such, the application for a license to possess and use byproduct material was provided with information that was not complete and accurate in all material respects. These inaccurate statements in the license application formed, in part, the basis for the issuance of the license on September 25, 1996. Further, the licensee continued to conduct NRC-licensed activities even though the licensee knew that it did not have an authorized user and RSO.

Although the NRC staff's review of the results of the OI investigation is ongoing, based on the above, the NRC has concluded that these violations were deliberate on the part of the licensee's President/Owner, and on the part of the licensee's consultant. By separate correspondence on this date, the NRC is issuing to the licensee's President/Owner, and to the licensee's consultant, Orders Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) Pending Further Order. The NRC must be able to rely on the licensee and its employees to comply with NRC requirements. Condition No. 13 of the license required that each use of licensed material be done by, or under the supervision of, Dr. Moskowitz as the authorized user named therein. NRC requires that the RSO named on the license implement a radiation safety program pursuant to 10 CFR 35.21. NRC also

requires that all communications between the licensee and the NRC be complete and accurate in all material respects, pursuant to 10 CFR 30.8.

It is admitted that the NRC conducted a new license inspection on January 29, 1997 at NMA. It is further admitted that the NRC then initiated an investigation and that Orders Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) were issued to Magdy Elamir, M.D. (NMA's president and owner) and Aharon Ben-Haim, Ph.D. (NMA's consultant) on July 31, 1997. However, insofar as Part II alleges either that NMA knowingly violated any relevant laws, regulations, or license restrictions, or that Dr. Elamir willfully or deliberately caused any such violations, these allegations are denied.

With respect to the specific allegations set forth in Part II, in February 1996, Dr. Elamir, acting on behalf of NMA, retained Dr. Ben-Haim, a physicist Dr. Elamir understood to be an expert in NRC regulations and licensing, as a consultant for NMA. Dr. Ben-Haim was to assist NMA in obtaining an NRC license, maintaining and operating equipment used in medical procedures subject to NRC regulation, training and supervising staff in performing those procedures, and ensuring compliance with NRC regulations (Exhibits A and B). In performing his contractual obligation to prepare NMA's state and federal license applications, Dr. Ben-Haim informed Dr. Elamir that NMA would need a qualified individual to serve as Radiation Safety Officer and authorized user.

In February 1996, Dr. Elamir's office was negotiating a professional radiology services agreement (Exhibit C) with the University of Medicine and

Dentistry/New Jersey ("UMDNJ"). Under the proposed agreement, UMDNJ would have read and interpreted MRI and other radiology images for imaging centers owned by Dr. Elamir, including NMA. During discussions in or about February 1996, Dr. Stephen Baker, Chairman of the Radiology Department at UMDNJ, suggested to Dr. Elamir that Dr. Moskowitz could serve as NMA's RSO and provided Dr. Moskowitz's phone number to Dr. Elamir. Dr. Elamir relayed this information to Dr. Ben-Haim and requested that Dr. Ben-Haim contact Dr. Moskowitz about becoming NMA's RSO and authorized user and to obtain the information on Dr. Moskowitz's qualifications which Dr. Ben-Haim had informed Dr. Elamir would be required as part of NMA's license applications. Dr. Ben-Haim later told Dr. Elamir that he had met with Dr. Moskowitz, had obtained from Dr. Moskowitz the documents necessary to complete NMA's license applications, and that everything was in order. Dr. Elamir understood from this and his earlier conversation with Dr. Baker that Dr. Moskowitz was ready and willing to serve as NMA's RSO and authorized user. Dr. Ben-Haim subsequently prepared the NRC license application which Dr. Elamir signed on behalf of NMA at Dr. Ben-Haim's direction. Thus, at the time the application was submitted to the NRC, NMA and Dr. Elamir believed that all of the information in the application, including the designation of Dr. Moskowitz as NMA's RSO and authorized user, was accurate and correct.

After NMA's NRC license was issued, NMA began engaging in NRC-licensed activities under the direction of NMA's consultant, Dr. Ben-Haim. These activities were undertaken in the belief that Dr. Ben-Haim and his staff were authorized,

through a delegation of authority from Dr. Moskowitz, to engage in NRC-licensed activities. When it learned for the first time on February 6, 1997 that Dr. Moskowitz had apparently not properly delegated his authority as RSO and authorized user to Dr. Ben-Haim, NMA promptly applied to the Commission for an amended license to replace Dr. Moskowitz as RSO and authorized user with Dr. Romolo Maurizi. The Commission issued an amended license on February 7, 1997, naming Dr. Maurizi NMA's RSO and authorized user.

To the extent that Part II contains allegations summarizing portions of Title 10 of the Code of Federal Regulations, these allegations are denied as stated; the regulations speak for themselves. NMA has insufficient knowledge or information to form a belief as to the truth of the allegations concerning what the NRC "learned" or when, and therefore denies them. To the extent that any remaining allegations in Part II remain unanswered, they are denied.

III.

Accordingly, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's requirements in 10 CFR 2.204 and 10 CFR 30.32(b), in order for the Commission to determine whether your license should be modified, suspended, or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements, the licensee is required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, within 20 days of the date of this Demand for Information, a response in writing and under oath or affirmation, describing why its license should not be suspended or revoked in light of: (1) the NRC findings described herein; and (2) the NRC Orders Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) Pending Further Order, which have been issued on this date to the licensee's President/Owner and to the licensee's consultant.

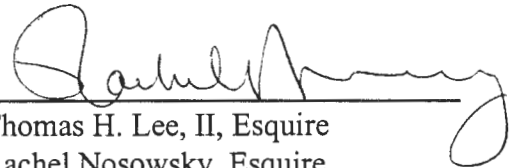
Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

After reviewing your response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

Newark Medical Associates, P.A. denies that it ever knowingly, willfully, or deliberately violated NRC requirements.

WHEREFORE, because NMA at all times acted in good faith, Newark Medical Associates, P.A.'s license should not be modified, suspended, or revoked.

Respectfully,

A handwritten signature in black ink, appearing to read "Thomas H. Lee, II", written over a horizontal line.

Thomas H. Lee, II, Esquire
Rachel Nosowsky, Esquire
DECHERT PRICE & RHOADS
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103
(215) 994-4000

Perry D. Robinson, Esquire
WINSTON & STRAWN
1400 L Street, NW
Washington, DC 20005-3502
(202) 371-5700

UNITED STATES
NUCLEAR REGULATORY COMMISSION

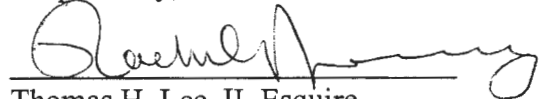
In the Matter of

NEWARK MEDICAL ASSOCIATES, P.A. : EA 97-308
Newark, New Jersey :

REQUEST FOR STAY OF ALL PROCEEDINGS

In light of the fact that this matter has been referred to the Department of Justice, Respondent, Newark Medical Associates, P.A., hereby requests that all other proceedings in this matter be stayed pending resolution of the referral. Dr. Magdy Elamir is subject to an Order prohibiting his involvement in NRC-licensed activities, and Newark Medical Associates has agreed not to engage in any NRC-licensed activities pending resolution of these matters. Therefore, the granting of a stay will not prejudice the NRC.

Respectfully,



Thomas H. Lee, II, Esquire
Rachel Nosowsky, Esquire
DECHERT PRICE & RHOADS
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103
(215) 994-4000

Dated: October 4, 1997

ATTORNEYS FOR
Newark Medical Associates, P.A.

Perry D. Robinson, Esquire
WINSTON & STRAWN
1400 L Street, NW
Washington, DC 20005-3502
(202) 371-5797

UNITED STATES
NUCLEAR REGULATORY COMMISSION

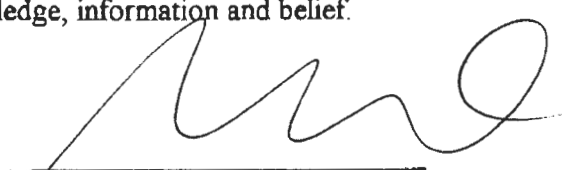
In the Matter of

NEWARK MEDICAL ASSOCIATES, P.A. : EA 97-308
Newark, New Jersey :

VERIFICATION

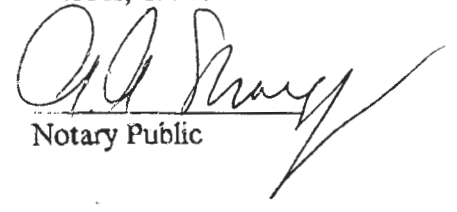
I, Magdy Elamir, M.D., affirm that the statements set forth in the attached

Answer are true and correct to the best of my knowledge, information and belief.



Magdy Elamir, M.D.
President/Owner
Newark Medical Associates, P.A.

Subscribed and sworn to
before me this 3RD day
of October, 1997.



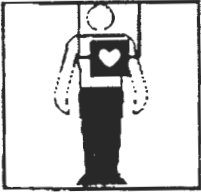
Notary Public

10-3-97

Date

ARTHIS AMEEN SHAREEF
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES JULY 15, 1999

EXHIBIT A



Aharon Ben-Haim, Physicist
52 Watchung Avenue
Upper Montclair, NJ 07043
Tel: (201) 783-3638
Fax: (201) 783-8479
Pager: (800)906-2646

Dr. Magdy Elamir
Submitted in Person

February 15, 1996

PROPOSAL

We offer to obtain on your behalf in the shortest possible time your State and Federal Material Licenses. At the same time, we will install your Hot Laboratory and establish the necessary Radiation Health procedures. The Hot Lab will be equipped with the necessary Measurement and Calibration equipment and materials, Counters, Meters and Waste Containers. We will prepare for State and NRC inspections.

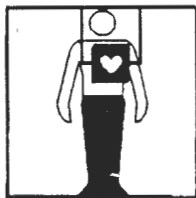
We will assure continuous monitoring of the Laboratory in compliance with the regulations of the Nuclear Regulatory Commission. We will train your staff, assist you in staffing requirements, perform all equipment tests, such as Dose Calibrator constancy, accuracy and linearity, assure that proper procedures are used in the handling of radioactive material, etc.

Sincerely yours,

A handwritten signature in cursive script that reads "Aharon Ben-Haim". The signature is written in dark ink and is positioned above the printed name.

Dr. Aharon Ben-Haim

EXHIBIT B



Aharon Ben-Haim, Physicist
52 Watchung Avenue
Upper Montclair, NJ 07043
Tel: (201) 783-3638
Fax: (201) 783-8479
Pager: (800)906-2646

Dr. Magdy Elamir
Submitted in Person

February 20, 1996

QUOTATION/AGREEMENT

I am pleased to submit the following quotation:

1. For a comprehensive maintenance service contract for your Elscint 409 A SPECT Gamma Camera, including physicist services, yearly \$16,000.00, payable quarterly at the beginning of each quarter. As a physicist, I will supervise your staff in all aspects related to the safe use of radioisotopes.

2. For a Complete Refurbished Hot Laboratory Unit comprising:

1 Calibrated Dose Calibrator for syringes and multidose vials.

1 Calibrated Survey Meter for Area Surveys, provided with Timer/Scaler for dpm counting (Wipe Tests)..

1 Lead glass shielded Dose Preparation Station.

1 Pair of Ustensil Prongs.

2 Syringe shields.

1 Desk top shielded syringe container.

1 Large shielded Waste Container.

Total price: \$7,500.00.

Terms: 50% Down with Purchase Order.
50% at Installation.

3. For preparation of State and NRC licenses: \$500.00. Due immediately.

By apposing your signature below on the right you are agreeing to my offer and its terms.

Sincerely yours,

For Newark Medical Associates

Dr. Aharon Ben-Haim, Physicist

Dr. Magdy Elamir

EXHIBIT C

MEDICAL SERVICES AGREEMENT

THIS AGREEMENT entered into this day of , 199
 , by and between the University of Medicine and Dentistry
 of New Jersey ("University") with offices at University
 Heights, Administration Complex #1, 30 Bergen Street,
 Newark, New Jersey 07107-3000 on behalf of the UMDNJ-New
 Jersey Medical School ("School") and Irvington MRI and
 Affiliated MRI Centers, with offices at
 , NJ ("Irvington").

WHEREAS, Irvington desires the services of experts in the
 delivery of radiology services;

WHEREAS, the School through its faculty in the Department
 of Radiology at the School possesses the expertise to
 provide the requisite services;

NOW THEREFORE, in consideration of the terms and
 conditions contained herein the parties hereto agree as
 follows:

radiology services:

- (a) interpretation of Irvington's magnetic resonance imaging studies and other radiology images for four (4) hours per day, Monday through Friday, excluding holidays and other days when School does not operate, subject to the following conditions:
- (b) that all magnetic resonance images shall be transported to School premises and returned to Irvington by Irvington at Irvington's expense. Reading and interpretation will be done by School on School premises.
- (c) that all other radiology images may either be transported to School premises and returned by Irvington at Irvington's expense or communicated by electronic means agreed upon by the parties. The cost of installation, maintenance and use of such electronic communication shall be borne equally by the parties.

(d) that all arrangements and expenses associated with the transcription and signing of radiology reports shall be the sole responsibility of Irvington.

(e) that School shall provide timely reports of interpretation results in writing or by electronic means, depending on the circumstances and the judgement of the radiologist.

2. Origination of Radiology Images Irvington and School agree that School shall not provide radiology services connected with images that are produced in Bayonne or Jersey City, New Jersey and that Irvington will not provide to School any images for interpretation that originated in those locations. School is contractually obligated to exclusive provision of radiology services in those locations to another party.

3. Term Services shall commence February 15, 1996 and shall continue to and shall be automatically renewed

annually thereafter, unless otherwise terminated pursuant to Section 7 herein or by mutual consent of the parties.

4. ~~Fee~~ Irvington agrees to pay the School according to the following schedule:

- (a) The cost to School of salary and fringe benefits of qualified radiologist's services to be provided pursuant to this agreement, which in the first year following execution shall be:

\$97,000.00 - base salary,

\$21,340.00 - fringe benefits

\$118,340.00 - total fee.

- (b) Fees and monthly payments by Irvington pursuant to this agreement shall be adjusted by School annually to reflect salary and fringe benefit adjustments of School.

- (c) For each contract year Irvington agrees to pay

to the School each month one-twelfth of the total fee pursuant to this section, payable no later than the 15th day of each month following first performance of services. Payment will be by check to the order of UMDNJ - New Jersey Medical School and mailed to: Department of Radiology, UMDNJ - New Jersey Medical School, 185 South Orange Avenue, Newark, NJ 07103-2714, Attn: Dr. Stephen Baker, Chair.

5. ~~Independent Contractor~~ The University shall remain an independent contractor for the term of this Agreement. Nothing contained herein shall be construed to make the University an employee or agent of the Irvington.

6. ~~Liability Coverage~~ Irvington shall be responsible throughout the duration of this Agreement and any renewals thereof, for maintaining a policy of insurance providing for professional and general liability insurance coverage of Irvington, its officers, employees, and agents and School and its employees who provide services pursuant to this agreement, subject to limits of coverage of not less than \$1,000,000/\$3,000,000. A

certificate of insurance shall be provided to the University naming the University as certificate holder and additional insured as its interests appear under this Agreement said insurance shall be deemed primary insurance.

The University shall provide for professional and general liability coverage insuring the University and its faculty, students and employees performing activities under this agreement through a Program of Self-Insurance providing limits of coverage of \$1,000,000/\$3,000,000 on an occurrence type basis pursuant to N.J.S.A. 59:1-1 et seq., the State of New Jersey Tort Claims Act. The University, upon request, shall furnish documentation certifying the funding mechanism of said Program.

7. **Default** In addition to any other rights in law or in equity, in the event that either party defaults in any term or condition of this Agreement, the non-defaulting party may terminate this Agreement upon 30 days written notice.

8. **Termination** University and Irvington shall have the right to terminate this Agreement upon Sixty (60) days

prior written notice without cause. In the event of any termination pursuant to this Agreement, University agrees to forward to Irvington all work performed as of the date of termination and Irvington agrees to immediate payment of all fees owed for work performed.

9. Non-Waiver The failure of either party to insist on strict performance of any of the provisions of this Agreement shall not be construed as a waiver of any other default whether or not of the same or similar nature.

10. Entire Agreement The parties agree that they are not relying upon any promises, understanding, warranties, circumstances, conduct, negotiations, expectations, representations or agreements, oral or written, express or implied, other than those expressly set forth herein; that this Agreement is complete integration and constitutes the entire agreement of the parties with respect to the subject matter hereof; that no amendments or other modifications of the Agreement shall be valid unless in writing and signed by an authorized officer of each party hereto; that this entire Agreement has been bargained for and negotiated; and the parties have read, understood and approved this Agreement in its entirety.

11. Governing Law This Agreement shall be governed by the laws of the State of New Jersey.

12. Notices to be sent pursuant to this Agreement shall be mailed, certified, as follows:

If to Irvington:

If to University:

Senior Vice President for
Administration & Finance
University of Medicine and
Dentistry of New Jersey
University Heights
65 Bergen Street,
Suite 1419
Newark, New Jersey 07107

With copies to:

Chairman
Department of Radiology
University of Medicine and
Dentistry of New Jersey
New Jersey Medical School
185 South Orange Avenue
Newark, New Jersey 07103

13. Non-Discrimination The provisions of Section 202 of Executive Order 11246 and Section 60-1.4, and 60-1.7, 60-1.8 of Chapter 60 of 41 Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of race, color, religion, sex or national origin; Section 60-741.4 of

Chapter 60 of 41 Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of physical or mental handicap; and Section 60-250.4 of Chapter 60 of 41 code of Federal Regulations, as amended, providing for the employment of disabled veterans and veterans of the Vietnam era, are hereby incorporated by reference to the same extent and with the same force and effect as it is set forth herein in full.

14. Non Collusion Both parties agree that no fee, commission, compensation gift or gratuity was paid or received regards to the solicitation of this Agreement, in contravention to N.J.S.A 52:13D-13 et seq.

IN WITNESS WHEREOF the parties hereto set their hand and seal the date first above written.

FOR Irvington

FOR UNIVERSITY OF MEDICINE
& DENTISTRY OF NEW JERSEY

Frederick J. Hammond, Jr.
Senior Vice President for
Administration & Finance

DATE

DATE

Recommended By:

Ruy Lourenco, M.D., Dean

DATE

DOCKETED
USNRC

UNITED STATES
NUCLEAR REGULATORY COMMISSION

'97 OCT -6 P5:23

OFFICE OF SECRETARY
RULEMAKING AND
ADJUDICATION STAFF

In the Matter of

NEWARK MEDICAL ASSOCIATES, P.A.
Newark, New Jersey

Docket No. 030-34066
License No. 29-30282-D1
EA 97-308

In the Matter of

MAGDY ELAMIR, M.D.
Newark, New Jersey

IA 97-064
IA 97-070

NOTICE OF APPEARANCE

This is to notify the commission of the appearance of Thomas H. Lee, II, Esquire and Rachel Nosowsky, Esquire of Dechert Price & Rhoads on behalf of Newark Medical Associates and Dr. Magdy Elamir in the above-captioned matters pursuant to 10 C.F.R. § 2.713(b). The following information is provided in support of our appearance:

1. Name/Address/Telephone Number

Thomas H. Lee, II, Esquire
Rachel Nosowsky, Esquire
DECHERT PRICE & RHOADS
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103
215/994-2994
215/994-2649

2. Name/Address/Telephone of Persons on Whose Behalf We Appear:

Associates	Newark Medical Associates, P.A. 810 Broad Street Newark, NJ 07102 201-242-8400	Dr. Magdy Elamir c/o Newark Medical 810 Broad Street Newark, NJ 07102 201-242-8400
------------	---	--

3. Basis of Eligibility for Appearance:

The Nuclear Regulatory Commission's regulations permit individuals, partnerships, corporations, and unincorporated associations to appear in an adjudication by an attorney at law. 10 C.F.R. § 2.713(b). Mr. Lee and Ms. Nosowsky represent Dr. Magdy Elamir and Newark Medical Associates, P.A. in the above-captioned actions, and are attorneys in good standing admitted to practice in the following jurisdictions:

Mr. Lee:

Admitted in Massachusetts
Admitted in Pennsylvania
Admitted in the U.S.D.C., District of Massachusetts
Admitted in the U.S.D.C., Eastern District of Pennsylvania
Admitted in the U.S. Court of Appeals, First Circuit
Admitted in the United States Claims Court
Admitted in the U.S. Court of Appeals, Third Circuit

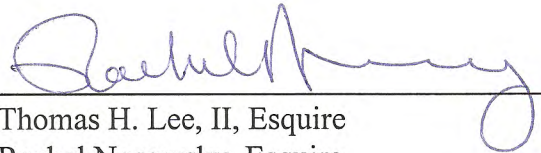
Ms. Nosowsky:

Admitted in Pennsylvania
Admitted in the U.S.D.C., Eastern District of Pennsylvania

4. Service in These Actions:

Pursuant to 10 C.F.R. § 2.708(e), service on Newark Medical Associates, P.A. and/or Dr. Magdy Elamir may be made on Mr. Lee and Ms. Nosowsky at their address, listed in Section 1 above.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Rachel Nosowsky", is written over a horizontal line.

Thomas H. Lee, II, Esquire
Rachel Nosowsky, Esquire
DECHERT PRICE & RHOADS
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103
215/994-40000

Dated: October 4, 1997

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION**

DOCKETED
USNRC

'97 OCT -6 P5:23

In the Matter of:)

NEWARK MEDICAL ASSOCIATES, P.A.)

Newark, New Jersey)

And)

MAGDY ELAMIR, M.D.)

Newark, New Jersey)

Docket No. 030-34066

License No. 29-30282-D1

EA 97-308

IA 97-064

IA 97-070

OFFICE OF SECRETARY
RULEMAKING AND
ADJUDICATION STAFF

NOTICE OF APPEARANCE

Notice is hereby given that the undersigned attorney herewith enters an appearance in the above-captioned matters. In accordance with 10 C.F.R. § 2.713(b), the following information is provided:

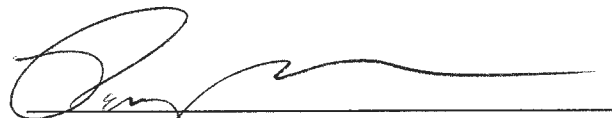
Name: Perry D. Robinson

Address: Winston & Strawn
1400 L Street, N.W.
Washington, D.C. 20005

Telephone Number: (202) 371-5797

Admissions: Admitted in Maryland
Admitted in the District of Columbia
Admitted in the U.S. Court of Appeals, District of Columbia Circuit

Name of Parties: Newark Medical Associates, P.A.
Magdy Elamir, M.D.
550 Summit Avenue
Jersey City, NJ 07306



Perry D. Robinson

Winston & Strawn

Counsel for Newark Medical Associates, P.A.

And

Magdy Elamir, M.D.

Dated at Washington, District of Columbia
this 2nd day of October, 1997

DOCKETED
USNRC

UNITED STATES
NUCLEAR REGULATORY COMMISSION

97 OCT -6 P5:24

In the Matter of

MAGDY ELAMIR, M.D.
Newark, New Jersey

IA 97-064

IA 97-070

OFFICE OF SECRETARY
RULEMAKING AND
ADJUDICATIONS STAFF

In the Matter of

NEWARK MEDICAL ASSOCIATES, P.A.
Newark, New Jersey

Docket No. 030-34086

License No. 29-30282-01

EA 97-308

CERTIFICATE OF SERVICE

I, Rachel Nosowsky, Esquire, certify that I caused to be served true and correct copies of the foregoing Answer to Order Superseding Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately), Answer to Demand for Information, Demand for Hearing and Request for Stay of All Proceedings, Request for Stay of All Proceedings, and Entries of Appearance upon the following by FedEx (next business day delivery):

Secretary

U.S. Nuclear Regulatory Commission
ATTN: Chief, Rulemaking and Adjudications
16th Floor, One White Flint North
11555 Rockville Pike
Rockville, MD 20852

Regional Administrator, Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

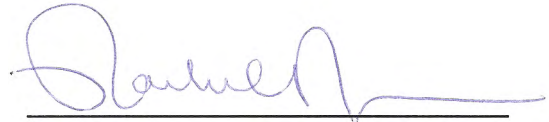
Secretary

U.S. Nuclear Regulatory Commission
ATTN: Docketing Service Branch
16th Floor, One White Flint North
11555 Rockville Pike
Rockville, MD 20852

Assistant General Counsel
for Hearings and Enforcement
U.S. Nuclear Regulatory Commission
15D3, One White Flint North
11555 Rockville Pike
Rockville, MD 20852

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
7H1, One White Flint North
11555 Rockville Pike
Rockville, MD 20852

Originals of each of these documents, except the Answer to Demand for Information and accompanying Request for Stay of All Proceedings, were served on the Secretary, ATTN: Chief, Rulemaking and Adjudications; the original Answer to Demand for Information and accompanying Request for Stay of All Proceedings was served on the Director, Office of Enforcement.



Rachel Nosowsky, Esquire
DECHERT PRICE & RHOADS
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103
(215) 994-2649

ATTORNEY FOR
Magdy Elamir, M.D.
Newark Medical Associates, P.A.

Dated: October 4, 1997

ongoing Procurement Initiatives, some of which include the following:

Consolidated Contracting Initiative

The CCI initiative emphasizes developing, using, and sharing contract resources to meet Agency objectives.

Single Process Initiative/Block Changes

The purpose of the Single Process Initiative/Block changes is to eliminate duplicative, highly-tailored or customer-unique requirements from contracts and adopt instead, a single process proposed by the contractor.

Contractor Performance Assessment Program

The Contractor Performance Assessment Program assesses the overall performance of NASA's top contractors across all of their major NASA contracts.

Performance Based Contracting

This initiative is focused on structuring an acquisition around the purpose of the work to be performed instead of how the work is to be performed or broad and imprecise statements of work.

Electronic Contracting

NASA's EC initiative is moving procurement transactions from traditional paper-based systems to electronic processing whenever possible. These transactions include solicitation and award documents as well as payment for our goods and services.

Tom Luedtke,

Deputy Associate Administrator for Procurement.

[FR Doc. 97-25100 Filed 9-19-97; 8:45 am]

BILLING CODE 7510-01-M

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

SES Performance Review Board

AGENCY: National Endowment for the Arts.

ACTION: Notice.

SUMMARY: Notice is hereby given of the names of members of the Performance Review Board for the National Endowment for the Arts. This notice supersedes all previous notices of the PRB membership of the Agency.

DATES: September 22, 1997.

FOR FURTHER INFORMATION CONTACT: Maxine C. Jefferson, Director of Human Resources, National Endowment for the Arts, 1100 Pennsylvania Avenue, N.W., Room 627, Washington, DC 20506, (202) 682-5405.

SUPPLEMENTARY INFORMATION: Sec. 4314(c)(1) through (5) of Title 5, USC, requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more SES Performance Review Boards. The Board shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any response by the senior executive, and make recommendations to the appointing authority relative to the performance of the senior executive.

The following persons have been selected to serve on the Performance Review Board of the National Endowment for the Arts:

Ana M. Steele, Deputy Chairman for Management and Budget
Laurence M. Baden, Director of Administration
Scott Shanklin Peterson, Deputy Chairman for Grants and Partnership
Alfred B. Spellman, Jr., Director of Office of Guidelines and Panel Operations

Maxine C. Jefferson,

Director of Human Resources, National Endowment for the Arts.

[FR Doc. 97-25062 Filed 9-19-97; 8:45 am]

BILLING CODE 7536-01-M

NUCLEAR REGULATORY COMMISSION

[IA 97-070]

In the Matter of Magdy Elamir, Newark, New Jersey; Order Superseding Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)

I

Magdy Elamir, M.D. (Dr. Elamir), is the Owner/President of Newark Medical Associates, P.A. (licensee). The licensee holds Byproduct Nuclear Material License No. 29-30282-01 (license) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The license authorizes possession and use of any radiopharmaceutical identified in 10 CFR 35.200 for any imaging and localization procedure approved in 10 CFR 35.200. The license was originally issued on September 25, 1996, and is due to expire on September 30, 2001.

II

During a new license inspection conducted on January 29, 1997, at the licensee's facility, several apparent violations of NRC requirements were identified. Subsequent to the inspection, the NRC initiated an investigation

which led the NRC to issue to Dr. Elamir, on July 31, 1997, an Order Prohibiting Involvement in NRC Licensed Activities (Effective Immediately) Pending Further Order (62 FR 43360). That Order was issued pending completion of the NRC staff review of the results of the investigation, which was conducted by the NRC's Office of Investigations (OI). The NRC staff's review of the results of the OI investigation is now complete.

III

The OI investigation focused, in part, on Dr. Elamir's actions in causing the licensee to be in violation of NRC requirements. The NRC learned during the investigation that Dr. Elamir transmitted an inaccurate license application (NRC Form 313, dated February 21, 1996) to the NRC. The license application named Newark Medical Associates as the prospective licensee. The license application was inaccurate in that it named Gerard W. Moskowitz, M.D. (Dr. Moskowitz), as the only authorized user and Radiation Safety Officer (RSO) without Dr. Moskowitz's consent or knowledge, and without Dr. Moskowitz's ever having been affiliated or associated with the licensee. Dr. Moskowitz did not ever perform the role of authorized user or RSO at the licensee's facility, and did not become aware that he was listed on the application and the license until notified by the NRC on February 6, 1997, more than four months after the license was originally issued. These inaccurate statements in the license application submitted by Dr. Elamir, formed, in part, the basis for the issuance of the license to Newark Medical Associates on September 25, 1996.

On October 17, 1996, Dr. Elamir notified the NRC by letter that Newark Medical Associates was initiating activities authorized by the license; and during the period from November 1996 through February 6, 1997, Dr. Elamir, in his capacity as president and owner of Newark Medical Associates, caused and permitted the licensee to conduct NRC-licensed activities even though he knew that the licensee did not employ the authorized user or the RSO named in the license application and, subsequently, on the NRC license, and that the named individual did not serve in these capacities. Based on the results of the OI investigation, the NRC has determined that Dr. Elamir's actions constitute violations of the Commission's requirements as follows:

A. 10 CFR 30.10(a)(2) requires, in part, that any licensee or employee of a licensee may not deliberately submit to

the NRC information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

During a February 6, 1997 telephone conversation between Dr. Elamir and an NRC inspector, Dr. Elamir stated to the NRC inspector that the Newark Medical Associates license was current with respect to the authorized user and RSO even though Dr. Elamir knew that the individual named on the license as the authorized user and RSO was not performing those duties and was not ever affiliated with the licensee in any capacity. This inaccurate statement was material because it had the ability to influence an NRC inspection.

B. 10 CFR 30.10 (a)(1), (c)(1), and (c)(2) require, in part, that any licensee or employee of a licensee not engage in deliberate misconduct that causes or, but for detection, would have caused a licensee to be in violation of: (1) Any rule, regulation, or order, or any term, condition, or limitation of any license issued by the Commission; or (2) any requirement, procedure, instruction, contract, purchase order or policy of a licensee.

1. 10 CFR 35.21 requires that a licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program; and requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

10 CFR 35.13 requires that a licensee apply for and receive a license amendment before it changes Radiation Safety Officers.

Byproduct Material License No. 29-30282-01, Condition 12, dated September 25, 1996 states that the Radiation Safety Officer for this License is Gerard W. Moskowitz, M.D.

On October 17, 1996, Dr. Elamir notified the NRC by letter that Newark Medical Associates was initiating activities authorized by the license; and, during the period from November 1996 through February 6, 1997, Dr. Elamir caused Newark Medical Associates to be in violation of the requirements in Section III.B.1 above by deliberately causing and permitting the licensee to conduct licensed activities even though Dr. Elamir knew that the individual designated as the RSO on the Newark Medical Associates license application and subsequent license did not ever serve as the Radiation Safety Officer under that license and was not ever affiliated with the licensee in any capacity.

2. 10 CFR 35.11 (a) and (b) permit an individual to use licensed material for medical use only in accordance with a specific license issued by the Commission or under the supervision of an authorized user as provided in 10 CFR 35.25.

Byproduct Material License No. 29-30282-01, dated September 25, 1996, states in Condition 13 that licensed material is only authorized for use by, or under the supervision of, Gerard W. Moskowitz, M.D.

On October 17, 1996, Dr. Elamir notified the NRC by letter that Newark Medical Associates was initiating activities authorized by the license; and during the period from November 1996 through February 6, 1997, Dr. Elamir caused Newark Medical Associates to be in violation of the requirements in Section III.B.2 above by deliberately causing and permitting licensed activities to be conducted by a technologist who did not hold a specific license issued by the NRC and who was not under the supervision of the authorized user specified on the license. Dr. Elamir knew that the individual designated as the only authorized user on the Newark Medical Associates license application and subsequent license did not ever serve as the authorized user under that license and was not ever affiliated with the licensee in any capacity.

IV

Based on the above, the NRC staff has concluded that Dr. Elamir deliberately caused the licensee to be in violation of NRC requirements by causing and permitting the licensee to conduct licensed activities in the absence of the authorized user and RSO named on the license application and on the NRC license. The NRC must be able to rely on the licensee and its employees to comply with NRC requirements. Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public, including patients receiving radiation from byproduct material for medical purposes, will be protected if Dr. Elamir were permitted at this time to be involved in NRC-licensed activities. Therefore, the public health, safety and interest require that Dr. Elamir be prohibited from any involvement in NRC-licensed activities for a period of five years. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of Dr. Elamir's conduct described above is such that the public health, safety and interest require that this Order be immediately effective.

V

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR 30.10, Part 35, and 10 CFR 150.20, *It Is Hereby Ordered That, Effective Immediately.*

1. The Order of July 31, 1997, is superseded, in its entirety.

2. Dr. Elamir is prohibited from engaging in NRC-licensed activities for a period of five years from July 31, 1997. This prohibition applies to Dr. Elamir as an officer, employee, contractor, consultant, or other agent of a licensee and includes, but is not limited to: (1) Any use of NRC-licensed materials; (2) supervising licensed activities, including (but not limited to) hiring of individuals engaged in licensed activities or directing or managing individuals engaged in licensed activities; (3) any involvement in radiation safety activities including (but not limited to) functions of the Radiation Safety Officer; and (4) development of license applications, procedures, and policies to meet license requirements, providing training to meet license requirements, and providing professional services to meet license requirements. NRC-licensed activities are those activities that are conducted pursuant to a specific or general NRC license, including, but not limited to, those activities of Agreement State licensees conducted in areas of NRC jurisdiction pursuant to the authority granted by 10 CFR 150.20.

3. If, as of July 31, 1997, Dr. Elamir was involved in NRC-licensed activities other than at Newark Medical Associates, P.A., he must: (1) Immediately cease such activities; (2) inform the NRC of the name, address and telephone number of the NRC-licensed entity or entities where the activities are being conducted; and (3) provide a copy of this order to all such NRC-licensed entities.

4. For any entities, other than Newark Medical Associates, P.A., where Dr. Elamir was involved in NRC-licensed activities for the period beginning three years prior to the date of this Order, Dr. Elamir must, within 30 days of the date of this Order, inform the NRC of the name, address and telephone number of the NRC-licensed entities where those activities were conducted.

5. For the five years immediately following the five year prohibition in paragraph V.2 above, the first time that Dr. Elamir is employed or involved in NRC-licensed activities following the five year prohibition, he shall notify the Director, Office of Enforcement, at the

address in Section VI below, prior to engaging in NRC-licensed activities, including activities under an Agreement State license when activities under that license are conducted in areas of NRC jurisdiction pursuant to 10 CFR 150.20. This notice shall include the name, address, and telephone number of the NRC or Agreement State licensee and the location where licensed activities will be performed; and shall include a statement as to why the NRC should have confidence that Dr. Elamir will not, in the future, commit deliberate violations of Commission requirements.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by the licensee of good cause.

VI

In accordance with 10 CFR 2.202, Dr. Elamir must, and any other person adversely affected by this Order may, submit an answer to this Order and may request a hearing on this Order, within 20 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Dr. Elamir or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Chief, Rulemaking and Adjudications, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to Dr. Elamir if the answer or hearing request is by a person other than Dr. Elamir. If a person other than Dr. Elamir requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Dr. Elamir or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Dr. Elamir may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. *An answer or a request for hearing shall not stay the immediate effectiveness of this order.*

Dated at Rockville, Maryland this 15th day of September 1997.

For the Nuclear Regulatory Commission.

Ashok C. Thadani,

Deputy Executive Director for Regulatory Effectiveness.

[FR Doc. 97-25080 Filed 9-19-97; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket 40-7102]

Finding of No Significant Impact for the Renewal of Source Material, License SMB-743, Shieldalloy Metallurgical Corporation, Newfield, New Jersey

The U.S. Nuclear Regulatory Commission is considering the renewal of the Source Material License SMB-743 for the continued operation of Shieldalloy Metallurgical Corporation (SMC), located in Newfield, New Jersey

Summary of the Environmental Assessment

Identification of the Proposed Action

The proposed action is the renewal of SMC's Source Material License SMB-743 for 5 years. With this renewal, the SMC facility will continue to produce specialty alloys, slag fluidizers, and

other products. The proposed action would permit SMC to possess up to 1,200,000 kilograms (kg) of thorium-232 and 180,000 kg of uranium-238, as requested in SMC's September 15, 1995, renewal application. As part of the proposed action, SMC would also continue to add radioactive materials to the temporary stockpiles of slag and baghouse dust currently stored at the site until a final disposition is approved by the commission. Although the continued storage of this material is evaluated as part of the environmental assessment (EA), the evaluation of environmental impacts from a final disposition method is outside the scope of this EA and will be addressed in a separate environmental action.

The Need for the Proposed Action

SMC performs a service for the commercial steel industry by producing speciality alloys, slag fluidizers, and other products. SMC is one of two domestic producers of ferrocolumbium (ferroniobium alloy), its main product from the licensed activities; ferrocolumbium is readily available from foreign producers, such as Brazil and, recently, the Confederation of Independent States (formerly the Soviet Union) and Canada. The element niobium can increase the strength of steel by more than 5,000 pounds per square inch (psi) with only a small addition of niobium (approximately 0.01 percent), thus allowing lighter weight alloys. Denial of the license renewal for the SMC facility is an alternative available to NRC, but would either require the construction of a new facility at another site or a possible dependence upon foreign imports of ferrocolumbium.

Environmental Impacts of the Proposed Action

The radiological impacts of the continued operation of the SMC facility were assessed by calculating the radiation doses to the maximally exposed individual located at the facility fence line and the collective radiation dose to the local population living within 80 kilometers (50 miles) of the plant site. The primary exposure pathway is release and transport of radioactive effluents to the air.

Doses From Routine Airborne Releases

SMC operates their process using two baghouses to filter airborne material: the Flex Kleen (FK) Baghouse and the American Air Filter (AAF) Baghouse. Atmospheric releases were determined from the two D-111 Baghouse stacks. Other potential release points including stored dust and slag piles were also