

MATERIALS LICENSE

Amendment No. 15

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

OFFICIAL RECORD COPY

Licensee		In accordance with the letter dated January 6, 1997,	
1. Nuclear Imaging Systems, Inc.		3. License Number 37-28453-01 is amended in its entirety to read as follows:	
2. 65 Valley Stream Parkway, Suite 300 Malvern, Pennsylvania 19355		4. Expiration Date July 31, 2005	
		5. Docket or Reference No. 030-31395	
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed	
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200 except generators and gas	B. As needed	
9. Authorized use			
A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.			
B. Any imaging and localization procedure approved in 10 CFR 35.200.			

CONDITIONS

10. A. Licensed material may be stored and possessed, incident to mobile activities, at the licensee's facilities located at 618 Delaware Avenue, Bethlehem, Pennsylvania; 1259 Cedar Crest Boulevard, Suite 200, Allentown, Pennsylvania; 740 South Chester Road, Suite C-1, Swarthmore, Pennsylvania; 506 Thomson Park Drive, Cranberry Township, Pennsylvania; 4A Great Meadow Lane, East Hanover, New Jersey; 5709 South Laburnum Avenue, Richmond, Virginia; 222 Schanck Road, Suite 2C, Freehold, New Jersey; 10 W. Baltimore Pike, Lansdowne, Pennsylvania; 1500 Lindaire Avenue, Mansfield, Ohio and 2241 Corsons Lane, Unit D, Plymouth Meeting, Pennsylvania;
- B. Licensed material listed in Item 6 may be used at clients' medical care facilities in the states of Pennsylvania, New Jersey, Delaware, Connecticut, Ohio and Virginia.
11. The Radiation Safety Officer for this license is Charles Gentile.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

37-28453-01

Docket or Reference Number

030-31395

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12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Robert C. Farmer, M.D.	35.100; 35.200
Bindukumarc Kansupada, M.D.	35.100; 35.200
James L. Tatum, M.D.	35.100; 35.200
Madhukar Pandya, M.D.	35.200 for cardiovascular clinical procedures
Joel S. Raichlen, M.D.	35.200 for cardiovascular clinical procedures
Suketu Nanavati, M.D.	35.200 for cardiovascular clinical procedures
M. Khalid Malik, M.D.	35.200 for cardiovascular clinical procedures
S. Chivukula, M.D.	35.100; 35.200
Joseph M. Ullman, M.D.	35.200 for cardiovascular clinical procedures
Albert Saul, M.D.	35.200 for cardiovascular clinical procedures
Jeffrey Cooper, M.D.	35.100; 35.200
Bruce Line, M.D.	35.100; 35.200
Brian McCandless, M.D.	35.100; 35.200
Naresh Gupta, M.D.	35.100; 35.200
Karen S. Kutoloski, D.O.	35.200 for cardiovascular clinical procedures
Shaival J. Kapadia, M.D.	35.200 for cardiovascular clinical procedures

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated February 24, 1995
- B. Letter dated May 9, 1995
- C. Letter dated June 6, 1995
- D. Letter dated July 14, 1995
- E. Letter dated August 30, 1995
- F. Letter dated October 27, 1995
- G. Letter dated July 1, 1996
- H. Letter dated September 20, 1996
- I. Letter dated January 6, 1997

Date

JAN 29 1997

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Michelle Beardsley

By

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

JAN 29 1997

Jeffrey Mandler
President/ CEO
Nuclear Imaging Systems, Inc.
900 E. 8th Avenue, Suite 200
King of Prussia, PA 19406

Dear Mr. Mandler:

This refers to your license amendment request. Enclosed with this letter are the amended licenses.

Prior to release of your old facility for unrestricted use you should be sure that the facilities meet the criteria in the enclosed "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material." You should submit a report of the results of the surveys you performed to this office and refer to this letter.

Please review the enclosed documents carefully and be sure that you understand and fully implement all the conditions incorporated into the amended licenses. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

License Nos. 37-28453-01/37-28453-02
Docket Nos. 030-31395/030-33417
Control Nos. 124090/124091

Enclosures:

1. Amendment No. 15
2. Amendment No. 07

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J. Mandler
Nuclear Imaging Systems, Inc.

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3. Guidelines for Decontamination of Facilities and
Equipment Prior to Release for Unrestricted
Use or Termination of Licenses for Byproduct, Source,
or Special Nuclear Material

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J. Mandler
Nuclear Imaging Systems, Inc.

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DOCUMENT NAME: R:\WPS\MLTR\L3728453

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Beardsley						
DATE	01/21/97		01/ /97		01/ /97		01/ /97

OFFICIAL RECORD COPY



Nuclear Imaging Systems

January 6, 1997

Michelle Beardsley
US NRC Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

030-31395
37-28453-d

Re : Amendment Request for Radioactive Materials License Number : 37-28453-01 / 02.

Dear Ms. Beardsley,

An amendment to the above referenced radioactive materials license is requested in order to:

1. Move the Swarthmore, PA location of use to the following address :

2241 Corsons Lane, Unit D
Plymouth Meeting, PA

No patient studies will be performed at this facility. This facility will be used as a base station for mobile cardiac nuclear medicine. A diagram of the facility is attached for your review.

2. Remove the Swarthmore, PA location from the license. A copy of the close-out survey will be forwarded to you at the time of the move described above, after the approval of this amendment. The quality control sources will be transferred to the Plymouth Meeting location at that time.

3. Add the following authorized user to the license :

a) Shaival J. Kapadia, MD
Dr. Kapadia's credentials are attached for your review.

4. Change the corporate address / phone number (effective Feb., '97) to :

Nuclear Imaging Systems, Inc.
65 Valley Stream Parkway, Suite 300
Malvern, PA 19355 phone: (800) 394-2620

All other aspects of the program will remain the same. I have enclosed \$880 for the license amendment fee. If you have any further questions please feel free to contact Jim Fongheiser of my staff at (610) 768-1555.

Sincerely,

Jeffrey Mandler, President / CEO

cc : Charles Gentile, RSO

124090

JAN 21 1997

Attachments : Plymouth Facility Diagram

Credentials for S. Kapadia

Amendment Fees

JAN -9 1997

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FAX REC'D

Nuclear Imaging Systems, Inc.
2241 Corsons Lane, Unit D
Plymouth Meeting, PA



SHAIVAL J. KAPADIA, M.D.

8711 Brawner Drive
Richmond, VA 23229
(804) 741-7653 (Home)

POST-DOCTORAL TRAINING:

- | | |
|-----------|---|
| 1993-1996 | Brown University / Rhode Island Hospital,
Providence, Rhode Island
Fellow in Cardiology
Skills include diagnostic catheterization, nuclear
cardiology, echocardiography including transesophageal
and stress echo, temporary pacemaker and Swan-Ganz
catheter placement. |
| 1990-1992 | Medical College of Virginia, Richmond, Virginia
Resident in Internal Medicine |
| 1989-1990 | Medical College of Virginia, Richmond, Virginia
Intern in Internal Medicine |

MEDICAL EDUCATION:

- | | |
|----------|--|
| May 1989 | University of Virginia, Charlottesville, VA
Doctor of Medicine.
Alpha Omega Alpha |
|----------|--|

UNDERGRADUATE EDUCATION:

- | | |
|----------|---|
| May 1985 | Johns Hopkins University, Baltimore, MD
Bachelor of Arts (Behavioral Biology) |
|----------|---|

EMPLOYMENT EXPERIENCE:

- | | |
|-----------|---|
| 1994-1996 | Cardiology Foundation, East Providence, Rhode Island
Nuclear stress testing |
| 1994-1995 | Rhode Island Hospital, Providence, Rhode Island
Emergency department physician |
| 1994-1996 | The Atrium, Providence, Rhode Island.
Supervision of stress testing and post MI cardiac
rehabilitation |
| 1992-1993 | Rappahannock General Hospital, Kilmarnock, Virginia
Hospital-based internist |

PRESENTATION:

"Presence of a Partial Coronary Stenosis Does Not Abolish The Protective Effect of Ischemic Preconditioning" abstract presented at the American College of Cardiology Annual Scientific Session in Orlando, Fla 3/26/96

PUBLICATION:

Kapadia, S., Terlato J., Most, A. Presence of a Partial Coronary Stenosis Does Not Abolish The Protective Effect of Ischemic Preconditioning. J Am Coll Cardiol. 1996;27: (Suppl A) 195A (abstract). Manuscript submitted to Circulation.

PROFESSIONAL SOCIETIES:

American College of Physicians, Member
American College of Cardiology, Affiliate
American Society of Nuclear Cardiology

LICENSURE AND CERTIFICATION:

1996	NRC licensure in clinical radioisotope training. Completed prerequisite 200 hours. Competent in cardiac perfusion imaging with thallium-201 and scintamibi-Tc 99m as well as first pass imaging/ gated blood pool scan
1992	Diplomate, American Board of Internal Medicine
1990	Diplomate, National Board of Medical Examiners
1990	Commonwealth of Virginia Medical Licensure (current)
1990	BLS/ACLS certification (current)

PERSONAL DATA:

Date of Birth:	May 14, 1964
Place of Birth:	Richmond, Virginia
Personal Data:	Married (Jill)

REFERENCES:

Available on request

Certificate of Participation

THIS IS TO CERTIFY THAT

SHAIVAL KAPADIA, M.D.

successfully completed the course for physicians entitled

Radioisotope Handling Techniques for Nuclear Medicine Procedures

for a total of two hundred hours of lectures,
demonstrations, and related assignments

SUBJECTS COVERED INCLUDE

Radiation Physics & Instrumentation
Radiation Protection
Mathematics Pertaining to the Use and
Measurement of Radioactivity

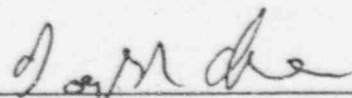
Instrumentation for Radionuclide Imaging
Radiation Biology
Radiopharmaceutical Chemistry

as specified in NRC Part 35

Sponsored by
Medical Physics, Department of Diagnostic Imaging
Rhode Island Hospital

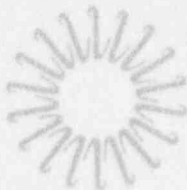


Dates: January 23 - May 1, 1995


Douglas R. Shearer, Ph.D., Course Director

Rhode Island Hospital

A *Grupa* Partner



593 Eddy Street
Providence, RI 02903
Tel 401 444-4000

12/6/96

Jim Fongheiser
Nuclear Imaging Systems
900 E 8th Ave
Suite 200
King of Prussia PA 194061

Dear Mr Fongheiser:

Shaival Kapadia MD fulfilled all the time required as specified by the NRC for authorized user under 35.970 (35.971, 35.200) b 2: 500 hours of supervised work experience under the supervision of an authorized user and under 3: 500 hours of supervised clinical experience under the supervision of an authorized user (Dr Richard Noto) at Rhode Island Hospital in Providence during time spent working in the Nuclear Medicine department at Rhode Island Hosp during his cardiology fellowship training.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lynne L Johnson".

Lynne L Johnson MD
Director Nuclear Cardiology
Rhode Island Hospital

A handwritten signature in cursive script, appearing to read "Richard Noto MD".

Richard Noto MD
Director Nuclear Medicine
Rhode Island Hospital

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02220
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 20050731
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: NUCLEAR IMAGING SYSTEMS, INC.
RECEIVED DATE: 970109
DOCKET NO: 3031395
CONTROL NO.: 124090
LICENSE NO.: 37-28453-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: -----
CHECK NO.: -----

3. COMMENTS

REF. 124091

SIGNED
DATE

M. A. Perkins
1/21/97

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1)

1. FEE CATEGORY AND AMOUNT: 7C 8440

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT -----
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED
DATE

LOG 12 I(92)
Check No. 6859
Amount 8440 Remaining 440
Fee Category 7C
Check Field AMD
Date Completed 1/29/97
By: BB

EXPEDITE - 07 for 1/29/97

1/29/97
Licensee called
me, requested
an expedite
I called it to
to process w/ review
and notified that
I entered the 07
Milestone BB