

APPROVED BY OMB, NO. 3145-0122 EXPIRES: 10-21-2019
Detailed instructions for response to comply with this regulatory collection required 4-8 hours. Submission of this application is necessary to determine that the applicant is qualified and that adequate provisions exist to protect the public health and safety. Send comments regarding burden estimate to the Records and Planning Policy Services Branch (15-FR) U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by internet e-mail to info@nrc.gov and to the Desk Officer, Office of Information and Regulatory Affairs, Room 3030A, 1215 Jefferson Avenue, Office of Management and Budget, Washington, DC 20503. If a response is required an information collection does not comply with currently valid OMB control number. The NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR ESTABLISHMENT OF SOURCE FACILITY FOR APPLICATIONS FILE

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDING
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, RHODE ISLAND, VERMONT, VIRGINIA, WEST VIRGINIA, WISCONSIN, WYOMING, SEND APPLICATIONS TO:

1200 NORTH WINDYBROOK DRIVE
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION 1
475 ALLENDALE ROAD
NORFOLK, VIRGINIA 23504-1415

IF YOU ARE LOCATED IN:

ILLINOIS, IOWA, KANSAS, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR PENNSYLVANIA, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION 2
2400 SPRINGFIELD ROAD, SUITE 200
LEAS, MO 64655-1402

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, DC, WISCONSIN, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION 4
615 RYAN PLAZA DRIVE, SUITE 100
AUSTIN, TEXAS 78761-4002

PERSONS OPERATING IN PERPETUUM (PERPETUUM) APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WANT TO FORFEIT AND USE LICENSES IN PERPETUUM (PERPETUUM) TO THE U.S. NUCLEAR REGULATORY COMMISSION IN PERPETUUM.

1. THIS IS AN APPLICATION FOR: (Circle appropriate box)
 A. NEW LICENSE
 B. AMENDMENT TO LICENSE NUMBER _____
 C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)
Ajay Agarwala, M.D.
906 Oak Tree Road
South Plainfield, NJ 07080

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
Ajay Agarwala, M.D.
906 Oak Tree Road
South Plainfield, NJ 07080

4. NAME OF PERSON TO WHOM LICENSED MATERIAL IS TO BE LOANED
Ajay Agarwala, M.D.
TELEPHONE NUMBER
(908) 222-8700

EXEMPT FROM THE THROUGH THE 42 11 11 PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIATION SAFETY PROGRAM
a. General and specific training of each physical form and to include all areas which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDUSTRY RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8. TRAINING FOR INDUSTRY WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSE FEE (See 10 CFR 170 and Section 170.33)
FEE CATEGORY: _____ AMOUNT ENCLOSED: _____

13. CERTIFICATION (Must be completed by Applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICER (INCLUDING THE CERTIFICATION ON BEHALF OF THE APPLICANT) SHOWN IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN COMPLIANCE WITH THE FEDERAL REGULATIONS, PARTS 21, 32, 33, 34, 35, 36, 37, 40 AND 41, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1949 (18 STAT. 749) MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPE PRINTED NAME AND TITLE: Ajay Agarwala, M.D. OWNER SIGNATURE: [Signature] DATE: 2/11/06

FOR NRC USE ONLY
TYPE OF FEE: [] FEE LETTER: [] FEE CATEGORY: [] ACCOUNT RECEIVED: [] CHECK NUMBER: [] COMMENTS: []
APPROVED BY: [] DATE: []

RECEIVED REGION 1

2006 FEB 7 PM 1:31

138443

NMCS/RGN MATERIALS-002

ITEM 5: RADIOACTIVE MATERIAL

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 35.100	Any	As needed
Any byproduct material permitted by 10 CFR 35.200	Any	As needed

ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

10 CFR 35.100	Medical Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required
10 CFR 35.200	Medical Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is Not Required

Authorized User

Use

Ajay Agarwala, M.D.

35.100, 35.200

Item 7 - Individual Responsible for Radiation Safety

Ajay Agarwala, M.D. is the Radiation Safety Officer and Authorized User for this license. He was most recently an Authorized user and RSO on the following licenses which are attached.

NRC Radioactive Materials License # 29 - 30952 - 01
Institute For Better Breathing

NJ Radioactive Materials License # 20832
Institute For Better Breathing

NYS Radioactive Materials License # 5168
Daniel Levy, M.D.

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

Pursuant to the Public Health Law and Part 16 of the New York State Sanitary Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing radioactive material(s) for the purpose(s), and at the place(s) designated below. The license is subject to all applicable rules, regulations, and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

1. Name	3. License Number
Daniel E. Levy, M.D., P.C.	5168
2. Address	4. a. Effective Date
788 Franklin Street	January 26, 2005
Valley Stream, New York 11580	b. Expiration Date
Attention: Ajay Agarwala, M.D.	January 31, 2015
Radiation Safety Officer	
	5. Reference Number
	DH No. 04-530

6. Radioactive Materials (element & mass no.)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at one time
A. Technetium 99m	A. Any	A. 500 millicuries (all forms combined)
B. Thallium 201	B. Thallous Chloride	B. 50 millicuries
C. Cobalt 57	C. Sealed Source	C. 20 millicuries
D. Cesium 137	D. Sealed Source	D. 500 microcuries

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 5168

9. Authorized use (unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2, above).
- A. and B. Determination of cardiac function.
- C. and D. Calibration of equipment.
10. A. Radioactive material listed in Item 6 shall only be used by:

Ajay Agarwala, M.D.
- B. Radioactive materials listed in Item 6 shall be used by Ajay Agarwala, M.D., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.
11. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license, in accordance with statements, representations, and procedures contained in the documents (including any enclosures) listed below:
- A. Application for New York State Department of Health Radioactive Materials License dated November 23, 2004, signed by Daniel E. Levy, M.D.
- B. Letter dated January 5, 2005, signed by Daniel E. Levy, M.D.
- The New York State Department of Health's regulations shall govern the licensee's statements in applications or letters unless the statements are more restrictive than the regulations.
12. A. Radioactive material shall be stored in a locked facility in the original shipping container, or a container providing equivalent radiation protection. Such a facility may be a cabinet, a safe, or a room, providing the facility is locked at all times when no activities are in progress relating to the use of the radioactive material. This includes periods of brief absence of personnel from a nuclear medicine department, laboratory, etc., where radioactive materials are used or stored.
- B. Radioactive materials shall not be stored in the same facilities with materials which might substantially increase the fire or explosion hazard of the storage space and its radioactive contents.

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 5168

13. A. Transportation of licensed radioactive material shall be subject to all regulations of the U.S. Department of Transportation and other agencies of the United States having jurisdiction insofar as such regulations relate to the packaging of radioactive material, marking and labeling of the packages, loading and storage of packages, monitoring requirements, accident reporting, and shipping papers.
- B. Transportation of low level radioactive waste shall be in accordance with the regulations of the New York State Department of Environmental Conservation as contained in 6 NYCRR Part 381.
14. The licensee shall have available an appropriate survey meter which shall be maintained operational and shall be calibrated before initial use and at subsequent intervals not exceeding twelve months by person(s) specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. Records of all calibrations shall be kept a minimum of five years.
15. Leak tests of sealed sources shall be performed in accordance with Section 16.10 (a)(4), New York State Sanitary Code (10 NYCRR 16). Off-site analysis of leak test samples shall be performed by persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. On-site analysis of leak test samples shall be in accordance with procedures approved by the Department.
16. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Affected radioactive waste shall be held for decay a minimum of ten half-lives.
- B. Prior to disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels will be removed or obliterated.
17. The licensee shall not administer technetium-99m to patients if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 5168

22. The licensee may receive, possess and use calibration and reference standards in accordance with section 16.123(e) of 10 NYCRR Part 16.
23. Nuclear Medicine Technologists who meet the criteria of 10 NYCRR 16.123(a)(3)(i) may perform parenteral injections of radioactive materials for diagnostic purposes under the supervision of a physician on the premises. Prior to allowing parenteral administration by a nuclear medicine technologist, the Radiation Safety Officer shall insure that the technologist is competent in the performance of parenteral administration. Records of this approval must be retained as long as the Nuclear Medicine Technologist is working under the license.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: **JAN 26 2005**
RD/AD:ks

By Robert E. Dansereau
Robert E. Dansereau, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

Item 9 B

License No.: NJSL-20832/01/000
Amendment No.: 000
Page 1 of 2

State of New Jersey

Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415, Trenton, NJ 08625-0415
Phone (609) 984-5462

New Jersey Radioactive Materials License

Pursuant to the New Jersey Radiation Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive or use the naturally occurring and/or accelerator produced material(s) (NARM) designated below; and to such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the State Department of Environmental Protection, now or hereafter in effect, and to any conditions specified below.

1. License No. NJSL-20832/01/000	2. Expiration Date 04/30/2005
3. Licensee: INSTITUTE FOR BETTER BREATHING	Address: Newark Liberty International Airport Building 340 Newark NJ 07105
Radiation Safety Officer: Ajay Agarwal, M.D.	County: Essex
Administrator: Manmohan Patel, M.D.	Telephone: (973) 596-1100
	Reference No.: 3900

RADIOACTIVE MATERIALS DATA (A)

6. Material: A. CO-57	Quantity: 35,000	Form: Sealed Source
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RADIOACTIVE MATERIALS DATA (B)

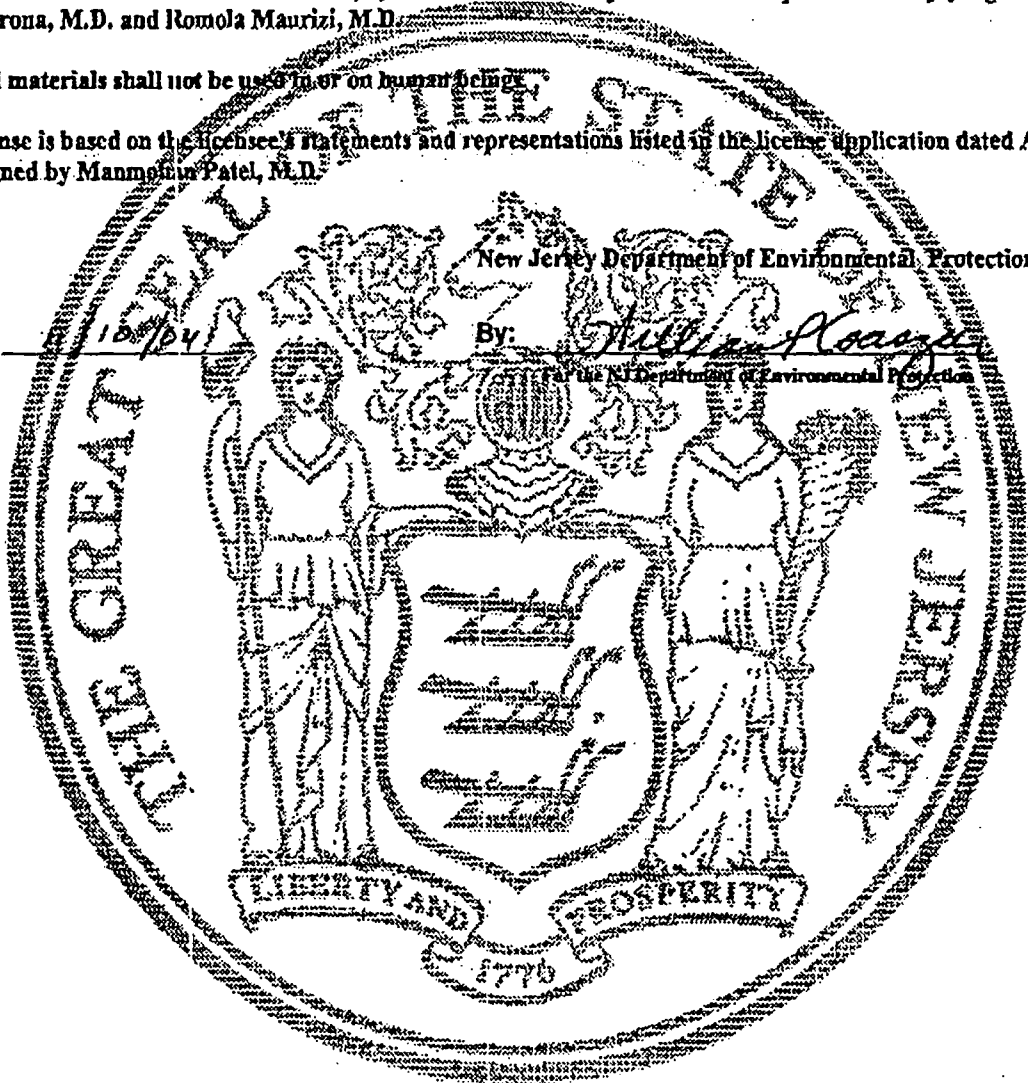
9. Authorized Use: A. For calibrating and checking of instruments.

Conditions begin on the following page

New Jersey Radioactive Materials License

- 10. Radioactive material shall only be used at Institute for Better Breathing, Newark Liberty International Airport, Building 340, Newark, New Jersey.
- 11. Radioactive material listed in Conditions 6, 7, and 8 shall be used by or under the supervision of Ajay Agarwala, M.D., Paul Verona, M.D. and Romola Maurizi, M.D.
- 12. Licensed materials shall not be used in or on human beings.
- 13. This license is based on the licensee's statements and representations listed in the license application dated August 23, 2004 signed by Manmohan Patel, M.D.

Date: 10/1/04 By: William Hoag
New Jersey Department of Environmental Protection Signature
For the NJ Department of Environmental Protection



MODEL PROGRAM For Radiation Safety Training

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. Licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. Worker's right to be informed of occupational radiation exposure and bioassay results.
9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.
- 10 Question and answer period.

The following will be trained initially, and then annually:

Nuclear Medicine Techs
EKG Techs
Nurses

ITEM 9

Radiation Monitoring Instruments

- (A) Radiation Survey Instruments will be calibrated yearly by a qualified person to perform such calibrations. (We will send out our meter to our radiopharmaceutical vendor, who sends it to a calibration laboratory that meet the requirements in 10 CFR 20.1501 and of 10 CFR 35.61.)
- (B) Radiation Well Counter will be calibrated yearly by our consulting physicist, who will follow nationally recognized standards or the Manufacturers recommendations.

The Survey meter is a Ludlum 14 with a 44-9 GM Pancake Probe. This unit will be used for Daily package surveys of incoming packages, daily area surveys, daily monitoring of hands and feet, and for monitoring waste prior to disposal.

The Well Counter is a Capintec CRC 15 W with a Capintec Well. This unit will be used for daily wiping of Incoming and outgoing radioactive packages, and for weekly area wipe testing for contamination.

We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

Dose Calibrator

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufactures instructions.

Gamma Camera

We will perform all Quality Control and Calibrations that are in accordance with nationally recognized standards and manufacturers recommendations.

Attachment **9A**
Facilities and Equipment

Hot Lab:

The hot lab is the location where radiopharmaceuticals are stored, prepared and dispensed. Lead bricks or lead lined storage modules are used to provide shielding where necessary. The hot lab has an "L" block present. Additional lead shielding is used around the "L" block where necessary. Absorbent, plastic backed paper is used to line the counter tops where radioactive material is used.

DOT shipping containers for the transport of . . . unit doses provide significant shielding. These will be used for storage of patient doses until their use unless a suitable alternative exists.

Storage of Radioactive Material and Waste:

Lead lined (1/8 inch) disposal cans are present in the hot lab areas for the storage of radioactive waste. Lead lined (1/8 inch), or equivalent, storage modules are present for the storage of radioactive material.

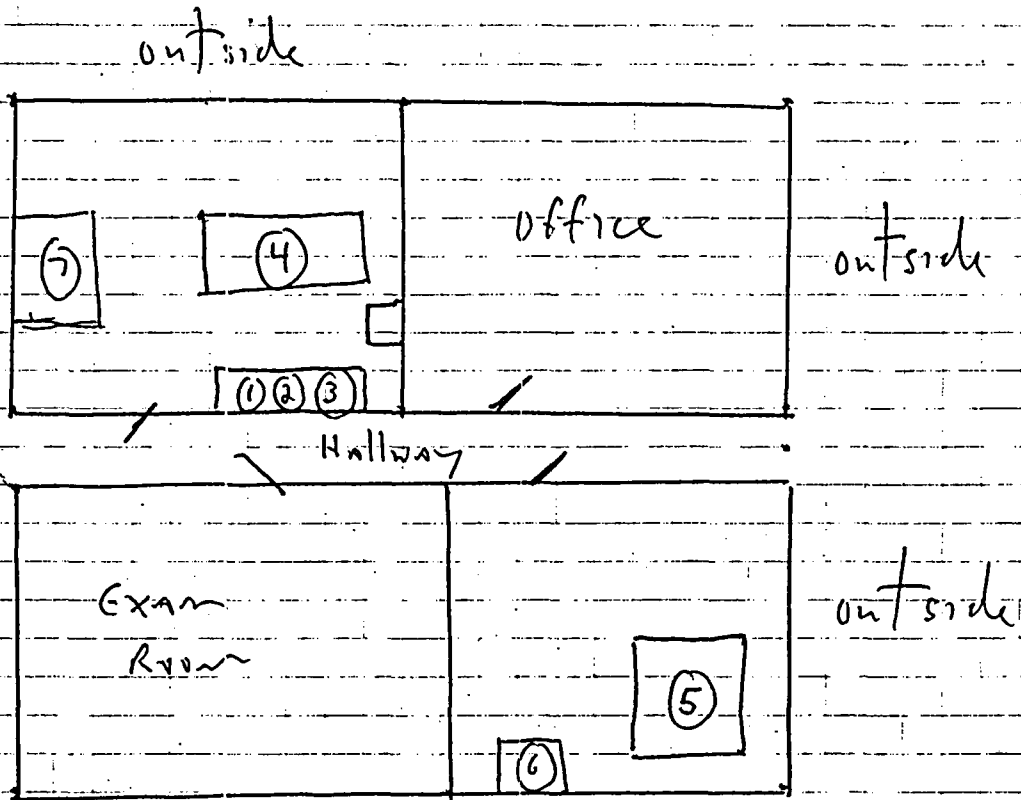
Additional Safety Equipment:

The following safety equipment is also present for use at the licensee's facility and at locations where radiopharmaceuticals are used.

syringe shields
disposable protective gloves
remote handling devices
lead shields for vial storage
lead lined storage modules

syringe carriers
absorbent pads
lead equivalent L-block
lead bricks (as needed)
lab coats

Ajay Agarwala, M.D.
906 Oak Tree Road
South Plainfield, NJ 07080



- 1 L-Block w lead shielding
- 2 Lead Lined Storage
- 3 Lead Lined Waste Container(s) : A) Sharps B) 5 Gallon Non-sharps
- 4 Treadmill
- 5 Stress Table/ Chair/ Injection Area
- 6 Imaging Camera / Imaging Chair
- 7 Camera / Computer Control

Item 10

Occupational Dose

We will provide dosimetry that meets the requirements listed under criteria in NUREG 1556, volume 9 "Consolidated Guidance about Materials License: Program Specific Guidance about Medical Use Licensees."

Area Surveys

We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

Safe Use of Unsealed Licensed Material

We have developed and will implement and maintain procedures for safe use of unsealed byproduct that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

Spill Procedure

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.

Item 11

Waste Management

We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

This is to acknowledge the receipt of your letter/application dated

2/1/2006, and to inform you that the initial processing which includes an administrative review has been performed.

NEW LICENSE APPLICATION (030 37144)
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 138443.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: Program Code: 02201
: Status Code: 3
: Fee Category: _____
: Exp. Date: 0
: Fee Comments: _____
: Decom Fin Assur Reqd: _
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
Applicant/Licensee: AGARWALA, AJAY, M.D.
Received Date: 20060217
Docket No: 3037144
Control No.: 138443
License No.: 29-31131-01
Action Type: New Licensee

2. FEE ATTACHED
Amount: _____
Check No.: /

3. COMMENTS
Signed M. A. Perkins
Date 2/21/2006

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /_/)

- 1. Fee Category and Amount: _____
- 2. Correct Fee Paid. Application may be processed for:
Amendment _____
Renewal _____
License _____
- 3. OTHER _____

Signed _____
Date _____