NRC FORM 313 (3-2009)
10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a 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 MATERIALS 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 DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

Br1

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

03035657

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

RECEIVED REGION 1 2011 MAR 28 AM 10:52

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER

✓ C. RENEWAL OF LICENSE NUMBER **06-30624-01**

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

John P. Seibyl, MD
Molecular NeuroImaging, LLC (MNI)
60 Temple Street, 8th floor
New Haven, CT 06510

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

60 Temple Street
Suites 8A and 9A
New Haven, CT 06510

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John P. Seibyl, MD

TELEPHONE NUMBER

(203) 401-4381

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maiximum amount which will be possessed at any one time.

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

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY **7C** AMOUNT ENCLOSED $ **0.00**

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 OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 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 -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
John P. Seibyl, MD; President, MNI		**03/25/2011**

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		

APPROVED BY DATE

574-761

NMSS/RGN1 MATERIALS-002

Items # 5. & # 6.

Byproduct Material	Chemical Form	Possession Limit	Purpose
Any material listed in 10 CFR 35.100	Any radiochemical listed in 10 CFR 35.100	As needed	Uptake, dilution and excretion procedure
Any material listed in 10 CFR 35.200	Any radiochemical listed in 10 CFR 35.200	As needed	Imaging and localization procedure
Any material listed in 10 CFR 35.300	Any radiochemical listed in 10 CFR 35.300	As needed	For research and development for submission of IND proposals for acceptance by the FDA

Item # 7

Individual Responsible for Radiation Safety:

Radiation Safety Officer: John Peter Seibyl, M.D.
Dr. Seibyl is certified by the American Board of Nuclear Medicine.
Attached is a copy of Dr. Seibyl's current Board Certification.

Item #8

Training for individuals working in or frequenting restricted areas:

Prior to working in restricted areas, an individual shall be appropriately trained in the cGMP guidelines, Radiation Safety, NIH human protection guidelines, corporate safety program, and OSHA as recommended of all staff.

Before an individual can perform cGMP activities, he/she must complete training in cGMP consisting of review of the cGMP (21 CFR 212) conducted by a currently authorized cGMP individual, and demonstrate understanding by written exams. If the individual would otherwise be qualified by previous education, training, and experience he/she may satisfy this requirement by completing a refresher training course. All persons engaged in manufacture and control of cGMP products must complete refresher training on an annual basis.

Individuals completing the cGMP training will have that documented by their attendance at the course and a certificate of successful completion issued by the instructor.

Radiation Safety training is given to all MNI staff on an annual basis and as part of their initial introduction to the workplace.

Item #9
Facilities and Equipment:

Attached are copies of our current departmental floor plans:

Equipment currently used within our departments follows:

Model Name	Type of Unit	Use
Picker Prism 3000	Gamma cameras	Patient imaging
Capintec CRC - multiple types	Dose calibrators	Dose Assay
Ludlum # 14-C	GM – meter	Area Survey
Wallac 1470 & 2480	NaI (Tl) Well Counters	Wipe Survey
Siemens HR+	PET camera	Patient imaging
Neurologica Inspira	Gamma camera	Patient imaging
ECAT EXACT HR+	PET camera	Patient imaging

Item # 10
Radiation Safety Program:
Facility Training Program (See 10 CFR 19.12, NRC Reg. Guide 10.8 Appendix A)

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.

Instructions for individuals in attendance will include:

1. Applicable regulations and license conditions
2. Areas where radioactive materials are used or stored
3. Potential hazards associated with radioactive materials in each area where the employee will work.
4. Appropriate radiation safety procedures
5. Our facility's in-house work rules
6. Each individual's obligation to report unsafe conditions to the RSO or his designee.
7. Appropriate response to emergencies or unsafe conditions
8. Worker's rights to be informed of occupational radiation exposure.
9. Location where notices, copies of pertinent regulations and copies of our license and license conditions are stored and/or posted
10. A question and answer period will be provided.

Calibration of Survey Instruments:
(See 10 CFR 35.51, NRC Reg Guide 10.8, Appendix B)
This facility has established and implemented the model procedures for the calibration of radiation survey instruments that was published in Appendix B to NRC Regulatory Guide 10.8, Rev 2.
We use RSCS in Stratham, NH for annual calibration of radiation survey instruments.

Calibration of Dose Calibrators
(See 10 CFR 35.50, NRC Reg Guide 10.8, Appendix C)
This facility has established and implemented the model procedures for the calibration of our dose calibrators that was published in Appendix C to NRC Regulatory Guide 10.8, Rev 2 with the following exceptions:

Linearity testing: We will continue to test dose calibrators for linearity before first use and upon repair over the range of doses from the highest to the lowest dose given to a patient. We will monitor bias voltage on a regular basis, as appropriate, in between these tests. We use Radserv, LLC for quarterly confirmation and audits of routine measurements obtained.

Personnel External Exposure Monitoring Program:
(See 10 CFR 20.1201-1302, NRC Reg. Guide 10.8. Appendix D)

1. The radiation safety officer (RSO), medical physicist or the RSO appointed designee will review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This review is reported to the Safety Committee during their regularly scheduled meetings and is included in the minutes. This procedure does not apply to back-up monitor records (i.e.: pocket ion chambers) The reviewer of personnel Dosimetry records will report any instances in excess of ALARA Level I guidelines
2. Individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film badge that will be processed by a NVLAP certified service on a monthly basis.
3. Individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a TLD extremity monitor that will be processed by a NVLAP certified service on a monthly basis.
4. Individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy will be issued a whole body monitor when caring for such patients.
5. Other individuals who are exposed to radiation on an occasional basis such as secretarial staff and nurses who care for patients who have received diagnostic dosages will not normally be issued exposure monitors unless they request one

Radiation Safety Committee Charter
(See 10 CFR 35.21-35.23, NRC Reg Guide 10.8, Appendix F)

This license is a privately owned facility, as such; a radiation safety committee is not required. However, all research involving human subjects is reviewed by an independent Institutional Review Board (IRB).

ALARA Policy and Procedure
(See NRC Reg 10.8 Appendix G)

This facility will issue the model ALARA program that was published in Appendix G of NRC Reg. Guide 10.8, Rev 2 with the following exceptions:

Area	Quarterly dose ALARA Level I	Quarterly dose ALARA Level II
Whole body-deep	125 mRem	375 mRem
Skin-shallow	1250 mRem	3750 mRem
Extremity dose	1250 mRem	3750 mRem
Eye dose	375 mRem	1125 mRem

These ALARA guidelines are in line with the maximum permissible occupational dose limits outlined in 10 CFR 20.1201(a).

Sealed Source Leak Testing
(See NRC Reg Guide 10.8, Appendix H)

This facility has issued the model program for the leak testing of sealed sources of radioactive materials as outlined in Appendix H of NRC Reg Guide 10.8, Rev 2.

Please note that:
1. Leak test samples will be taken by our medical physicist.
2. Samples will be analyzed in a well spectrometer counter (NaI(Tl)).
3. The counting efficiency of this unit will be routinely monitored by the medical physicist.
4. Any samples that are in excess of 0.005 μCi of removable contamination will be treated as radioactive and disposed of accordingly.

Rules for the Safe Use of Radiopharmaceuticals:
(See 10 CFR 35.60, 35.61, NRC Reg Guide 10.8, Appendix I)

We have implemented the model safety rules for the use of radiopharmaceuticals that were published in Appendix I to NRC Reg Guide 10.8, Rev 2.

Spill Procedures – Major and minor spills.
(See 10 CFR 35.21, NRC Reg Guide 10.8, Appendix J)

Minor Spills of Liquids and Solids:

1. Notify persons in the area that a spill has occurred. event the spread of contamination by covering the spill with absorbent paperClean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and other contaminated disposable material in the bag.
2. Survey the area wit a low range radiation survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination
3. Report the incident to the Radiation Safety Officer (RSO) or his designee.
4. The RSO or his designee will follow up on the cleanup of the spill and will review the reports as prepared by the nuclear medicine or radiochemistry department

Major Spills of Liquids and Solids.

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry
5. Notify the RSO or his designee immediately.
6. Decontaminate personnel by removing contaminated clothing, and flushing contaminated skin with lukewarm water then washing with mild soap. If contamination remains induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released with perspiration.
7. The RSO or his designee will supervise the cleanup of the spill and will prepare a report and develop and implement corrective procedures and training as necessary.

Relative Hazards of Common Radionuclides
(See NRC Reg Guide 10.8, Appendix J-1)

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedures based on the following table. Spills above the limits listed in the following table are to be considered major, below are considered minor

Radionuclide	Millicuries	Radionuclide	Millicuries

P-32	10.0	Tc-99m	100.0
Cr-51	100.0	In-111	100.0
Co-57	100.0	I-123	10.0
Co-58	10.0	I-125	10.0
Fe-59	10.0	I-131	1.0
Cu-64	10.0		
Co-60	1.0	Yb-169	10.0
Ga-67	100.0	Lu-177	100.0
Se-75	10.0	Hg-197	100.0
Sr-85	10.0	Au-198	10.0
Sr-89	10.0	Tl-201	100.0
Y-90	100.0		

Ordering and Receipt of Radioactive Materials
(See 10 CFR 20.1906, NRC Reg Guide 10.8, Appendix K)

We have established and implemented the model procedure for the order and receipt of radioactive materials that was published in Appendix K to the Regulatory Guide 10.8, revision 2.

Acceptable package radiation levels:

Label	Package Surface	1-meter from surface
White – I	0.5 mR/hr	--
Yellow – II	50.0 mR/hr	1.0 mR/hr
Yellow – III	200.0 mR/hr	10.0 mR/hr

Records of Byproduct Materials Use:
Radiopharmaceutical Records
(See 10 CFR 35.53 , NRC Reg Guide 10.8, Appendix M)

We have established and implemented the model procedure for unit dosage records that was published in Appendix M.1 to Regulatory Guide 10.8, Rev 2.

Procedure for Area Surveys
(See 10 CFR 35.70, NRC Reg Guide 10.8, Appendix N)

Procedure
We have established and implemented the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Rev 2.

Action Levels

Dose rate Action levels:	Area	Dose Rate
	Hot lab	>= 5 mR/hr
	Imaging rooms	>= 2 mR/hr

Storage rooms	>= 2 mR/hr
Uncontrolled areas	>= 0.5 mR/hr
Chemistry	>= 5 mR/hr

Contamination control action levels (net dpm/100 sq cm)

Area	Gamma emitters	I-131; I-125; beta emitters
Unrestricted areas	2000	200
Personal clothing	2000	200
Restricted areas	20,000	2,000
Skin	20,000	2,000
Lab coats	20,000	2,000

Procedures for use of radioactive gases
(NRC Reg Guide 10.8, Appendix O)

Not Applicable

Radiopharmaceutical Therapy Procedures
(NRC Reg Guide 10.8, Appendix P)

Not applicable

Implant Safety Procedures
(NRC Reg Guide 10.8, Appendix Q)

Not applicable

Item # 11

Waste Management:
(See 10 CFR 20.2001-20.2007, 10 CFR 35.92, NRC Reg Guide 10.8, Appendix R)

We have established and implemented the general guidance and model procedures for waste disposal that are published in Appendix R to Regulatory Guide 10.8, Rev 2.

Item # 12

License Fees
Fee Category_7C "Renewal" Amount Enclosed $__NA___

The American Board of Nuclear Medicine

Incorporated 1971

Attests that

John P. Seibyl

A Diplomate of the American Board of Nuclear Medicine
has demonstrated continuing Scholarship in

Nuclear Medicine

And is Hereby Recertified,
For the period 2004 through 2014

Michael M. Graham
Chairman

Christopher J. Palestro, MD
Secretary-Treasurer

05998
Number

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

3/25/2011, and to inform you that the initial processing which includes an administrative review has been performed.

☑ REGION 06-30624-01
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** 57461.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader