



Molecular Imaging Services, Inc.

"Excellence in Patient Care through State of the Art Imaging"

Branch 1

May 16, 2012

U. S. Nuclear Regulatory Commission
Region I DNMS
Licensing Assistance Team
2100 Renaissance Blvd.
King of Prussia, PA 19406

RE: License Amendment Request
License No. 07-30790-01
Docket No. 030-36176
Molecular Imaging Services, Inc.

RECEIVED
REGION 1
2012 MAY 18 PM 3:48

License Reviewers:

The following action to the above mentioned radioactive materials license is requested:

The addition of Andra Popescu, M.D. as an authorized user for materials and uses listed in 35.200. Copies of Dr. Popescu's preceptor information is enclosed.

The addition of David S. Grubbs, M.D. as an authorized user for materials and uses listed in 35.100 and 35.200. Dr. Grubbs is currently listed as an authorized user on NRC Materials License number 07-31076-01 of which a copy is enclosed.

Any questions regarding the above matter may be directed to Mr. Steve Henry, consultant, Krueger-Gilbert Health Physics, Inc. at (410) 692-9806 or to Mr. Frank DiGregorio, RSO, at (302) 750-3668.

Sincerely,

Mr. Frank DiGregorio
Radiation Safety Officer

577597

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, and 35.590]APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User

ANDRA POPESCU, MD

State or Territory Where Licensed

DELAWARE

Requested Authorization(s) (check all that apply)

☐ 35.100 Uptake, dilution, and excretion studies☒ 35.200 Imaging and localization studies☐ 35.500 Sealed sources for diagnosis (specify device _____)**PART I – TRAINING AND EXPERIENCE**
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

☐ **2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

b. Supervised Work Experience.

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

☐ 35.290☐ 35.390 + generator experience in 32.290(c)(1)(ii)(G)

ANDRA POPESCU, MD

NRC FORM 313A (AUD)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☒ 3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	200-HOUR AUTHORIZED USER COURSE FOR PHYSICIANS NUCLEAR EDUCATION ONLINE UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES -SEE CERTIFICATE-	100	NOV 2009 THRU JUNE 2011
Radiation protection	11	36	11
Mathematics pertaining to the use and measurement of radioactivity	11	22	11
Chemistry of byproduct material for medical use (not required for 35.590)	11	37	11
Radiation biology	11	23	11
Total Hours of Training:		218	

- b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience		Total Hours of Experience: 700	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	CHRISTIANA CARE HEALTH SERVICES NRC LICENSE # 07-12153-02	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	3/9/2009 TO 4/5/2009
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	EXPERIENCE WAS DURING NUCLEAR CARDIOLOGY ROTATIONS PERFORMED ON DATES SHOWN AT RIGHT.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11 AND 4/6/09 TO 5/3/09

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	CHRISTIANA CARE HEALTH SERVICES NRC # 07-12153-02 (NUCLEAR CARDIOLOGY ROTATIONS)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	AS ABOVE AND 10/19/2010 TO
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	11	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11/15/2010 TO 2/7/2011
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	11	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	3/6/2011 TO 5/3/2011
Administering dosages of radioactive drugs to patients or human research subjects	11	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6/20/2011 TO
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	11	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	AS ABOVE

Supervising Individual

TIMOTHY A. MANZONE, MD, JD

License/Permit Number listing supervising individual as an authorized user

NRC LICENSE 07-12153-02

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).

☐ 35.190 ☐ 35.290 ☐ 35.390 ☒ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

☒ I attest that ANDREA POPESCU MD has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

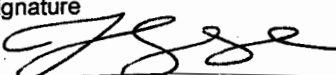
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

☒ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.190 ☐ 35.290 ☐ 35.390 ☒ 35.390 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
TIMOTHY A. MANZONE MD		302-733-1540	1-26-2012
License/Permit Number/Facility Name			
NRC LICENSE 07-12153-02 CHRISTIANA CARE HEALTH SERVICES			

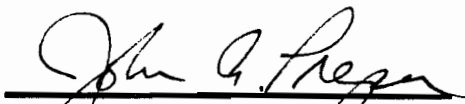
Certificate of Completion

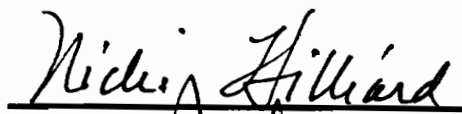
The University of Arkansas for Medical Sciences
and the
University of New Mexico Health Science Center
certify that

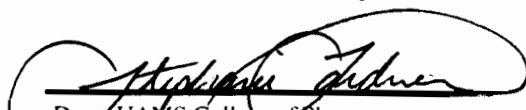
Andra Popescu, MD

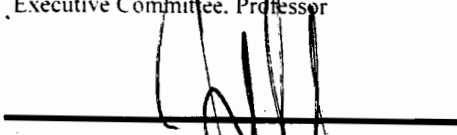
has completed the 200 hours of didactic education
requirements for Authorized User education as
specified by the Nuclear Regulatory Commission.

Authorized User of Radioactivity
Education and Training


Dean, UNM College of Pharmacy


Executive Committee, Professor


Dean, UAMS College of Pharmacy


Executive Committee, Associate Professor

June 20, 2011

neo

Nuclear
Education
Online

**University of Arkansas for Medical Sciences
and
The University of New Mexico Health Sciences Center**

Nuclear Education for Authorized Users

Andra Popescu

Didactic Courses	Nuclear Physics	Instrumentation	Radiochemistry	Radiation Safety	Radiation Biology	Total
Radiation Physics & Instrumentation	50	47		3		100
Radiation Protection				36		36
Math & Measure of Radioactivity	12	5		5		22
Radiation Biology					23	23
Radiochemistry			37			37
TOTALS	62	52	37	44	23	218

Program dates: November 2009 – June 2011

Nicki Hilliard

Nicki Hilliard, Pharm.D., BCNP
Professor of Nuclear Pharmacy

Jeffery Norenberg
Jeffery Norenberg, Pharm.D., M.S., BCNP
Professor of Nuclear Pharmacy

Revised April 2006

NUCLEAR MEDICINE

Fax 302/338856

Apr 10 2012 01:04pm P002/002

MATERIALS LICENSE

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.

Licensee	In accordance with the letter dated January 26, 2006,
1. David S. Grubbs, M.D.	3. License No. 07-31076-01
	is amended in its entirety to read as follows:
2. Omega Professional Center G36 Omega Drive Newark, Delaware 19713	4. Expiration Date: September 30, 2015
	5. Docket No: 030-36998

- | | | |
|---|----------------------------------|--|
| 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 permitted by 10 CFR 35.100 | A. Any | A. As needed |
| B. Any byproduct material permitted by 10 CFR 35.200 | B. Any | B. As needed |

9. Authorized use:

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at Omega Professional Center, G36 Omega Drive, Newark, Delaware.
- 11. The Radiation Safety Officer (RSO) for this license is David S. Grubbs, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License No.
07-31076-01Docket No.
030-36998Amendment No.
01

B. The following individuals are authorized users for medical use as indicated:

Authorized UserMaterial and Use

David S. Grubbs, M.D.


35.100; 35.200

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) for establishing decommissioning financial assurance.
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."
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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 August 12, 2005 [ML052270413]
B. Letter dated September 6, 2005 [ML052510800]
C. Letter dated January 26, 2006 [ML060370545]

For the U. S. Nuclear Regulatory Commission

Date March 1, 2006

By


Bryan A. Parker
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Wednesday, March 01, 2006 10:13:33 AM

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

May 16, 2012, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment

☒ 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** 577597.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.