

N
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NM182

10/03/08

Nuclear Regulatory Commission
Licensing Assistance Team
Nuclear Materials Safety Branch
475 Allendale Road
King of Prussia, PA 19406

29-30500-01MD
03034840

Re- Mail Control number 142802

I refer to the above mail control number, re amendment to add Mr. Andrew Lewie as an authorized user and to request expedited action on this matter. This allows us to accommodate vacation and work schedules with greater ease. Mr. Lewie was already approved and added to our New Jersey State Radioactive Materials License #10649/01 as of 9/23/08.

A copy of the original application and supporting documents are appended for ease of reference.

Your cooperation will be greatly appreciated.

Any questions or concerns, please feel free to contact me at (973)664-9696.

Thank you


Ken Ali

Radiation Safety Officer
Nuclear Diagnostic Products
101 Roundhill Drive
Rockaway, NJ 07866
Ph. (973)-664-9696
Fax. (973)-664-9699
E-mail: kena@ndprx.com

101 Roundhill Drive
Rockaway, New Jersey 07866

(973) 664-9696
(973) 664-9699 Fax

142802



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9/08/08

Nuclear Regulatory Commission
Licensing Assistance Team
Nuclear Materials Safety Branch
475 Allendale Road
King of Prussia, PA 19406

Re- RAM License number 29-30500

I refer to the above License and request the following amendment;

- ❖ Andrew J. Lewie, R.Ph. as an Authorized Nuclear Pharmacist.

Mr. Lewie is a licensed pharmacist in the State of New Jersey. He recently completed 214 hours of classroom instruction in Nuclear Pharmacy and the safe handling and use of Radioactive Materials, administered by the Ohio State University, College of Pharmacy. Mr. Lewie has also successfully completed over eight hundred(800) hours of supervised centralized nuclear pharmacy training at this facility. He has clearly and satisfactorily demonstrated that he has the ability and competency to function independently as an Authorized Nuclear Pharmacist (10CFR35.55) and operate a nuclear pharmacy (10CFR35.980).

Please find appended, a copy of Mr. Lewie registration certificate from the New Jersey State Board of Pharmacy, along with other documents supporting his completion of the minimum of 700 hours of training and experience in Nuclear Pharmacy.

Any questions or concerns, please feel free to contact me at (973)664-9696.

Thank you

 Ken Ali
 Radiation Safety Officer
 Nuclear Diagnostic Products
 101 Roundhill Drive
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N
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9/8/08

Mr. Ken Ali
Radiation Safety Officer
Nuclear Diagnostic Products
101 Roundhill Drive
Rockaway, NJ 07866

Re: Andrew J. Lewie, R.Ph

Dear Mr. Ali.

This letter serves to inform you that Mr. Andrew J. Lewie, R.Ph. has been training under my direct supervision as well as other professional staff members at this facility. To date, he has completed well over eight hundred(800) hours handling unsealed radioactive material in addition to overall pharmacy responsibilities. He has also successfully completed approximately two hundred fourteen(214) hours of didactic material administered by Ohio State University, College of Pharmacy(schedule of training attached).

Mr. Lewie has clearly and satisfactorily demonstrated that he has the ability and the competency to function independently as an Authorized Nuclear Pharmacist (10CFR35.55) and to operate a Nuclear Pharmacy(10CFR35.980). I strongly recommend that our Radioactive Materials License be amended to include Mr. Andrew J. Lewie as an Authorized Nuclear Pharmacist.

Any questions, please feel free to contact me immediately.

Thanks



Mark Novembre, RPh. Pharmacy Manager

101 Roundhill Drive
Rockaway, New Jersey 07866

(973) 664-9696
(973) 664-9699 Fax

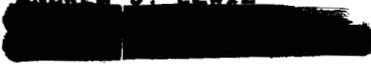
THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER WITH A MULTICOLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

**State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs**

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

ANDREW J. LEWIS



FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacist

10/26/2007 TO 04/30/2009
VALID

Signature of Licensee/Registrant/Certificate Holder

28R102528800

LICENSE/REGISTRATION/CERTIFICATION #

ACTING DIRECTOR

PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.

NAME: Andrew Lewie

DATE: 09/08/2008

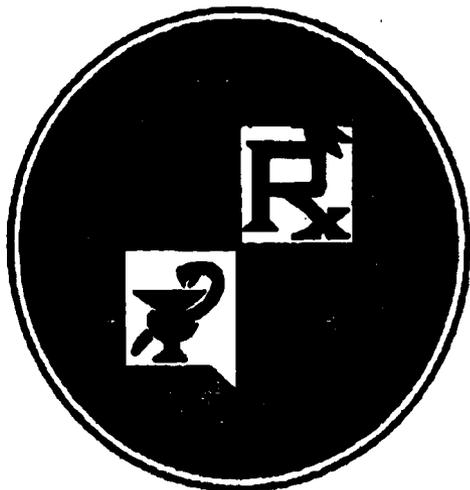
Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

ISOTOPE	MAXIMUM ACTIVITY HANDLED	USE See key below 1,2,3,4,5,6,7	EXPERIENCE Actual clock hours (include date range of experience)	WHERE EXPERIENCE GAINED
Mo-99	15 Ci	1,7	740 (4/08-9/08)	Nuclear Diagnostic Products Rockaway, NJ
Tc-99m	80 Ci	3,4,5,6,7	740 (4/08-9/08)	
I-131	1 Ci	1,3,4,5,6	220 (5/08-9/08)	
Xe-133	100 mCi	1,3,4,5,6	60 (5/08-9/08)	
I-123	50 mCi	1,3,4,5,6	200 (4/08-9/08)	
Ga-67	100 mCi	1,3,4,5,6	740 (4/08-9/08)	
Tl-201	200 mCi	1,3,4,5,6	740 (4/08-9/08)	
Co-57	5 mCi	1,2	5 (4/08-9/08)	
Cs-137	200 uCi	1,2	5 (4/08-9/08)	
Ba-133	250 uCi	1,2	1 (4/08-9/08)	
In-111	2 mCi	1,3,4,5,6	250 (4/08-9/08)	

Key for "Use"; the number or numbers entered under "use" should correspond to the handling experience for each isotope:

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and if appropriate, instruments used to measure alpha- or beta-emitting radionuclides.
3. Calculating, assaying, and safely preparing dosages for patients or human research subjects.
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material.
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures.
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.
7. Eluting Tc-99m from generator systems, assaying the eluate for Tc-99m and for Mo-99 contamination, and assaying the eluate with reagent kits to prepare Tc-99m labeled radioactive drugs.


Supervisor/Preceptor



The Ohio State University
College of Pharmacy
and
University Medical Center
Department of Pharmacy



By this certificate warrants that

Andrew Joseph Lewie

has satisfactorily fulfilled all requirements
and completed the prescribed course

Nuclear Pharmacy Certificate Program

September 5, 2008

George N. Kintle
Director, Nuclear Pharmacy
Associate Professor of Pharmacy



Robert W. Buegg
Dean, College of Pharmacy

Gerald L. Cobb
Executive Director
Council of Ohio Colleges of Pharmacy

Janice C. Wakala
Chair, Pharmacy Practice
and Administration



**THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER**



NUCLEAR PHARMACY CERTIFICATE PROGRAM

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

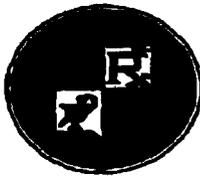
Name: Andrew Joseph Lewie

Location of Training	Dates of Attendance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
The Ohio State University, Columbus, OH	August 11, 2008 through September 5, 2008	Nuclear Pharmacy Certificate Program	214	88	45	20	22	39
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category) TOTAL HOURS			214	88	45	20	22	39

Authorized Nuclear Pharmacist/Authorized User:

George H. Hinkle
George H. Hinkle, RPh, MS, BCNP, FASHP, FAPhA

DATE: September 5, 2008



**THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER**



**NUCLEAR PHARMACY CERTIFICATE PROGRAM
RADIONUCLIDE HANDLING EXPERIENCE**

Name: Andrew Joseph Lewie

Date: September 5, 2008

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

RADIONUCLIDE	RADIOACTIVITY	USE see below	EXPERIENCE Actual clock hours (Include date range of experience)	LOCATION
Mo-99	10 Curies	1,2,3,4,5,6,7	8/11/08	The Ohio State University Medical Center Columbus, OH
Tc-99m	8 Curies	1,2,3,4,5,6,7	through	
I-131	200 mCi	1,2,3,4,5,6	9/5/08	
I-123	1 mCi	1,2,3,4,5,6		
Ga-67	25 mCi	1,2,3,4,5		
Tl-201	50 mCi	1,2,3,4,5		
In-111	7.5 mCi	1,2,3,4		
Sr-89	5 mCi	1,2,3,4,5,6		
Sm-153	100 mCi	1,2,3,4,5,6		
F-18	200 mCi	1,2,3,4,5,6		
Cs-137	0.2 mCi	1,2,5		
			TOTAL HOURS: 40 hours	

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each radionuclide.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys.
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if applicable, instruments used to measure alpha- or beta-emitting radionuclides.
3. Calculating, assaying and safely preparing dosages for patients or human research subjects.
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material.
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures.
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys and wipe tests.
7. Eluting Tc99m from generator systems, assaying the eluate for Tc99m and for Mo99 and processing the eluate with reagent kits to prepare Tc99m labeled radioactive drugs.

Authorized Nuclear Pharmacist:

George H. Hinkle
George H. Hinkle, RPh, MS, BCNP

Date: September 5, 2008