

NUCLEAR DIAGNOSTIC PRODUCTS

Attentive Services • Competitive Prices

9/08/08

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

Br. 2

Re- RAM License number 29-30500

25
-01MD 03034940

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
Rockaway, NJ 07866
Ph. (973)-664-9696
Fax. (973)-664-9699
E-mail: kena@ndprx.com

2008 SEP 12 AM 11:06

RECEIVED
REGION 1

101 Roundhill Drive
Rockaway, New Jersey 07866

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

142802

NMSS/RGN! MATER. ALS-002



Attentive Services • Competitive Prices

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

A handwritten signature in black ink, appearing to read 'Mark Novembre', is written over a horizontal line.

Mark Novembre, RPh. Pharmacy Manager

101 Roundhill Drive
Rockaway, New Jersey 07866

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

THIS DOCUMENT IS THE PROPERTY OF THE NEW JERSEY BOARD OF PHARMACY
BACKGROUND AND MULTIPLE SECURITY CHECKS HAVE BEEN PERFORMED

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

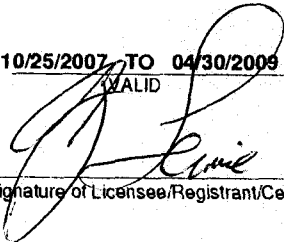
THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

ANDREW J. LEWIE
[REDACTED]


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

10/25/2007 TO 04/30/2009
VALID


Signature of Licensee/Registrant/Certificate Holder

28RI02528800

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


Director, Nuclear Pharmacy
Associate Professor of Pharmacy


Executive Director
Council of Ohio Colleges of Pharmacy



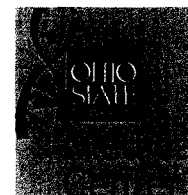

Dean, College of Pharmacy


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

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

9/8/08, and to inform you that the initial processing which includes an administrative review has been performed.

☒ **Amendment (29-30300-01MD)**
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** 142802.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.