

N

**NUCLEAR
DIAGNOSTIC
PRODUCTS**

Attentive Services • Competitive Prices

9/03/07

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

03034940

J-6

Re- RAM License number 29-30500-01MD

Ken

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

- ❖ Add Timothy M. Davis, Pharm. D. as an Authorized Nuclear Pharmacist.

Mr. Davis 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. Davis 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. Davis' registration certificate from the New Jersey State Board of Pharmacy informing him of his success and registration as a licensed pharmacist, 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

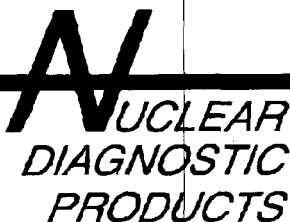
Ken Ali
Radiation Safety Officer

140885

NMSS/RGN1 MATERIALS-002

101 Roundhill Drive
Rockaway, New Jersey 07866

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



Attentive Services • Competitive Prices

9/6/07

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

Dear Mr. Ali,

Please note that staff pharmacist Mr. Matthew Cahir RPh, has given notice of his resignation effective 9/14/07. In lieu of this, I recommend that you request expedited action from all regulatory agencies to add Mr. Timothy M. Davis as an Authorized Nuclear Pharmacist to our Radioactive Materials Licenses. This would ensure timely and adequate staffing arrangements as a consequence of Mr. Cahir's departure.

Thanks

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

Rodney Prosser
Vice President

101 Roundhill Drive
Rockaway, New Jersey 07866

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



Attentive Services • Competitive Prices

9/5/07

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

Re: Timothy M. Davis, Pharm D.

Dear Mr. Ali.

This letter serves to inform you that Mr. Timothy M. Davis, Pharm D. 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. Davis 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). Having recently passed the NJ Board of Pharmacy exams, I strongly recommend that our Radioactive Materials License be amended to include Mr. Timothy M. Davis 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

N

NUCLEAR DIAGNOSTIC PRODUCTS

Attentive Services • Competitive Prices

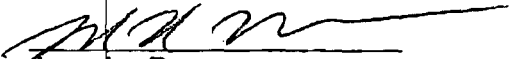
NAME: Tim DavisDATE: 9/5/2007

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

Mo-99	15 Ci	1,7	740 (6/05-7/06)	Nuclear Diagnostic Products Rockaway, NJ
Tc-99m	80 Ci	3,4,5,6,7	740 (6/05-7/06)	
I-131	1 Ci	1,3,4,5,6	220 (4/06-7/06)	
Xe-133	100 mCi	1,3,4,5,6	60 (4/06-7/06)	
I-123	50 mCi	1,3,4,5,6	200 (6/05-7/06)	
Ga-67	100 mCi	1,3,4,5,6	740 (6/05-7/06)	
Tl-201	200 mCi	1,3,4,5,6	740 (6/05-7/06)	
Co-57	5 mCi	1,2	5 (6/05-7/06)	
Cs-137	200 uCi	1,2	5 (6/05-7/06)	
Ba-133	250 uCi	1,2	1 (4/06-7/06)	
In-111	2 mCi	1,3,4,5,6	250 (4/06-7/06)	

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.

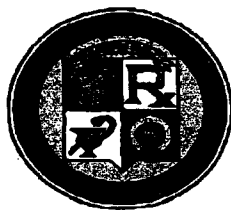


Supervisor/Preceptor

MARK NOVEMBRES

101 Roundhill Drive
Rockaway, New Jersey 07866

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



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



NUCLEAR PHARMACY CERTIFICATE PROGRAM

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Timothy Davis

Location of Training	Dates of Attendance	Course Title	Total Clock Hours	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 6, 2007 through August 31, 2007	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: August 31, 2007

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER WITH A SECURITY PATTERN
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

Timothy M. Davis

FOR PRACTICE IN NEW JERSEY AS A(N) Pharmacist

07/28/2007 TO 04/30/2009
VALID

28R103151400

LICENSE REGISTRATION CERTIFICATION #

PLEASE DETACH HERE
IF YOUR LICENSE/REGISTRATION/
CERTIFICATE ID CARD IS LOST
PLEASE NOTIFY:
Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

Signature of Licensee/Registrant/Certificate Holder

ACTING DIRECTOR

Timothy M. Davis

EXPIRATION DATE 2009

YOUR LICENSE/REGISTRATION CERTIFICATE NUMBER IS 28R103151400. PLEASE USE IT IN ALL
CORRESPONDENCE TO THE DIVISION OF CONSUMER AFFAIRS. USE THIS SECTION TO REPORT ADDRESS
CHANGES. YOU ARE REQUIRED TO REPORT ANY ADDRESS CHANGES IMMEDIATELY TO THE ADDRESS NOTED
BELOW

Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

PRINT YOUR NEW ADDRESS OF RECORD BELOW
YOUR ADDRESS OF RECORD IS THE ADDRESS THAT WILL PRINT ON
YOUR LICENSE/REGISTRATION CERTIFICATE AND IT MAY BE MADE
AVAILABLE TO THE PUBLIC

PRINT YOUR NEW MAILING ADDRESS BELOW
YOUR MAILING ADDRESS IS THE ADDRESS THAT WILL BE USED BY THE
DIVISION OF CONSUMER AFFAIRS TO SEND YOU ALL CORRESPONDENCE

HOME ☐
BUSINESS ☐

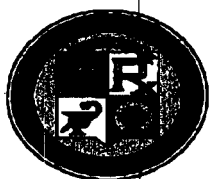
HOME ☐
BUSINESS ☐

TELEPHONE
INCLUDE AREA CODE

TELEPHONE
INCLUDE AREA CODE

If the law governing your profession requires the current license/registration/certificate to be displayed, it should be
within reasonable proximity of your original license/registration/certificate at your principal office or place of
business.

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



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



NUCLEAR PHARMACY CERTIFICATE PROGRAM

RADIONUCLIDE HANDLING EXPERIENCE

Name: Timothy Davis

Date: August 31, 2007

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	8/6/07	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	8/31/07	
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: August 31, 2007



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



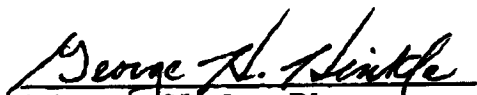
By this certificate warrants that

TIMOTHY M. DAVIS, PHARM.D.

has satisfactorily fulfilled all requirements
and completed the prescribed course

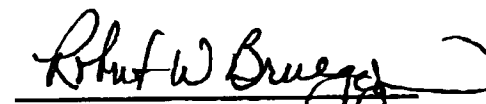
Nuclear Pharmacy Certificate Program

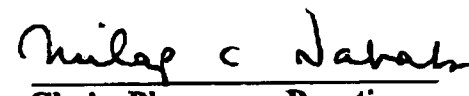
August 31, 2007


George H. Hinkle
Director, Nuclear Pharmacy
Associate Professor of Pharmacy


Gerald L. Cable
Director, Experiential Programs
College of Pharmacy




Robert W. Bruegg
Dean, College of Pharmacy


Nilay C. Sabharwal
Chair, Pharmacy Practice
and Administration