

TELEPHONE (505) 345-3551



May 16, 1984

Jenny M. Johansen
Nuclear Materials and Safeguards Branch
Region I
U.S. Nuclear Regulatory Commission
King of Prussia, Pennsylvania 19406

P.O. BOX 25141
ALBUQUERQUE, NEW MEXICO 87125

RE: License number 37-18461-01MD (Philadelphia)

Dear Ms. Johansen:

On behalf of Nuclear Pharmacy, Inc., I would like to request that the above license be amended to include Robert Grobinski and Joseph Nacchio as authorized users. Statements of training and experience have been enclosed for your review. Also enclosed, please find a check that includes the fee for this and another amendment.

Should you require additional information, please feel free to contact me.

Thank you for your assistance in this matter.

Sincerely,

NUCLEAR PHARMACY, INC.

Steven Dessel
Steven Dessel, R.Ph.

Director of Radiation Safety and Compliance

Enclosures

SD/gav

cc: Central File
Reading File
License Files
B. Crescenzi
C. Floyd
E. McCall

RECEIVED BY LFMB	
Date..	5/29/84
Log..	May 16 I
By...	Brown
Orig. To...	
Action Compl.	7/30/84

Applicant...	820
Check No...	820
Amount/Fee Category	#80 (#40-3B)
Type of Fee	Amendment
Date Check Rec'd.	5/29/84
Received By	Brown

02431
for #10
20-21227-01
M10

8406270165 840618
NMS LIC30
37-18461-01MD PDR

02430

"OFFICIAL RECORD COPY"

MAY 21 1984

MLIP

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

Robert Grobinski

2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE

3. CERTIFICATION

SPECIALTY BOARD
ACATEGORY
BMONTH AND YEAR CERTIFIED
CPennsylvania State Board
of Pharmacy

Pharmacist

Prospective Date:
August 1984

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	53	48
b. RADIATION PROTECTION	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	26	28
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	10	22
d. RADIATION BIOLOGY	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	10	22
e. RADIOPHARMACEUTICAL CHEMISTRY	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	22	44

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		See Attached		

EXPERIENCE WITH RADIATION

Robert Grobinski

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
Tc-99m Pertechnetate	50Ci	Temple University Hospital-Nuc.Med.Dept. Pharmacy- Experimental Nuclear Pharmacy, Inc. Philadelphia, PA	573 hrs. 500 hrs. 768 hrs.	- Research, experimental - Preparation of radio- pharmaceuticals for clinical use - Compounding and dispens- ing for patients and hospitals on a pre- scription order
Tc-99m Labeled Products	500mCi/product	"	"	"
Xe-133	8Ci	"	"	"
I-131 Sodium Iodide	1Ci	"	"	"
I-131 HSA	600mCi	"	"	"
I-131 Hippuran	100mCi	"	"	"
I-131 Rose Bengal	100mCi	"	"	"
I-125 Sodium Iodide	50mCi	"	"	"
Tl-201	100mCi	"	"	"
I-123 Sodium Iodide	1Ci	"	"	"
Se-75	50mCi	"	"	"
Yb-169 DTPA	500mCi	"	"	"

EXPERIENCE WITH RADIATION

Robert Grobinski

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
P-32 Products	100mCi/product	Same as previous page	Sames as previous page	Same as previous page
Cr-51 Products	20mCi/product	"	"	"
Co-57,57,60 Cyanocobalamin	10mCi	"	"	"
Ga-67	500mCi	"	"	"
In-111 DTPA	10mCi	"	"	"
Mo-99/Tc-99m Generators	50Ci	"	"	"

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

Joseph Nacchio

2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE

3. CERTIFICATION

SPECIALTY BOARD
ACATEGORY
BMONTH AND YEAR CERTIFIED
CPennsylvania State Board
of Pharmacy

Pharmacist

Prospective Date:
August 1984

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	53	48
b. RADIATION PROTECTION	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	26	28
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	10	22
d. RADIATION BIOLOGY	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	10	22
e. RADIOPHARMACEUTICAL CHEMISTRY	Temple University School of Pharmacy Philadelphia, PA 12/81 to 5/82 12/82 to 5/83 8/82 to 12/82	22	44

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		See Attached		

EXPERIENCE WITH RADIATION

Joseph Nacchio

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
Tc-99m Pertechnetate	50Ci	Temple University Pharmacy-Experimental	500 hrs.	<ul style="list-style-type: none"> - Research, experimental - Preparation of radio-pharmaceuticals for clinical use - Compounding and dispensing for patients and hospitals on a pre-scripture order
		Nuclear Pharmacy, Inc. Philadelphia, PA	800 hrs.	
Tc-99m Labeled Products	500mCi/product	"	"	"
Xe-133	8Ci	"	"	"
I-131 Sodium Iodide	1Ci	"	"	"
I-131 HSA	600mCi	"	"	"
I-131 Hippuran	100mCi	"	"	"
I-131 Rose Bengal	100mCi	"	"	"
I-125 Sodium Iodide	50mCi	"	"	"
Tl-201	100mCi	"	"	"
I-123 Sodium Iodide	1Ci	"	"	"
Se-75	50mCi	"	"	"
Yb-169 DTPA	500mCi	"	"	"

EXPERIENCE WITH RADIATION

Joseph Nacchio

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
P-32 Products	100mCi/product	Same as previous page	Sames as previous page	Same as previous page
Cr-51 Products	20mCi/product	"	"	"
Co-57,57,60 Cyanocobalamin	10mCi	"	"	"
Ga-67	500mCi	"	"	"
In-111 DTPA	10mCi	"	"	"
Mo-99/Tc-99m Generators	50Ci	"	"	"

Radiation Safety Short Course 15 hours of lecture & demonstrations

January 11 & 12

<u>Subjects</u>	<u>RSO Staff</u>	<u>Room</u>
Announcements	"	B-52
Introduction to Radiation	"	"
Coffee Break		
Biological Effects of Radiation Plus Radiation Risk and Pregnancy	"	"
Lunch		
Protection By Time, Distance, and Shielding	"	"
Lab Techniques and Model Lab	"	"
Coffee Break		
Decontamination	"	"
Radiation Accidents and Emergencies	"	"
Distribution of Radiation Safety Handbook for Take Home Study	"	"
Temple University Radiation Safety Office Plus Institutional, Local, State and Federal Regulations	"	"
Introduction to ALARA	"	"
Coffee Break		
Counting and Monitoring Instruments Plus Film "Radiation Detection By Ionization"	"	"
Demonstration of Use of Ionization Chamber, G.M. Detector, Proportional Counter & Scintillation Counter	"	"
Lunch (Viewing of video tape "Lab Techniques, Waste Disposal & Personnel Exposure Monitoring" during lunch hour optional)	"	"
Scintillation Counting Plus Film "Liquid Scintillation Counting" + (tentative) LSC - Use Demonstration	"	"
Coffee Break		
Examination (can use lecture notes and handout)	"	"
Discussion of Examination (tentative)	"	"

Useful Information for Attendees

1. Radiation Safety Office is in Room B-41. Telephone number (for messages) is 221-4927.
2. Vending machines are located on the second and fourth floors.
3. This course is offered quarterly and serves as an introduction to the material. More extensive treatment is given in P449, Isotope Methodology, offered in the fall semester (4 s.H.).

TENTATIVE LECTURE SCHEDULE

<u>DATE</u>	<u>TOPIC</u>
Jan. 19	Introduction, Course Requirements, Scope of Nuclear Pharmacy
Jan. 20	Nature of matter, Basic atomic structure, Types of radiation
Jan. 26	Units of radioactivity measurement, Kinetics of radioactive decay, basic radiation dosimetry concepts
Jan. 27	Biological Effects of radiation (Videotape)
Feb. 2	Instruments for detection of radiation
Feb. 3	Personnel dosimetry and Principles of radiation protection
Feb. 9	Production of radiopharmaceuticals and their procurement (Fission products, nuclear reactors, cyclotron products)
Feb. 10	Radionuclide generator technology, technetium chemistry and quality control
Feb. 16	Biological mechanisms radionuclides used to produce their response
Feb. 17	Therapeutic Radiopharmaceuticals
Feb. 23	Diagnostic Radiopharmaceuticals
Feb. 24	Diagnostic Radiopharmaceuticals
Mar. 1	Diagnostic Radiopharmaceuticals
Mar. 2	Diagnostic Radiopharmaceuticals
Mar. 15	FINAL EXAMINATION

Supplementary study guides will be provided when necessary.

Syllabus for: Introduction to Nuclear Pharmacy Course#P239; 30 hours
of lecture and 45 hours of laboratory
Tentative Lecture Schedule

Jan. 16	Overview of nuclear pharmacy, Review atomic & nuclear structure
Jan. 23	Modes and kinetics of radioactive decay
Jan. 30	Interaction of radiation with matter
Feb. 6	Production of radiopharmaceuticals
Feb. 13	Gas ionization detection systems
Feb. 20	Scintillation detection systems
Feb. 27	EXAM (1 hr.) Gamma scintillation spectrometry
Mar. 12	Other techniques for detection (liquid scintillation, autoradiography, semi-conductors)
Mar. 19	Radiation dosimetry
Mar. 26	Standards for radiation protection
Apr. 2	Regulatory agencies, record-keeping and quality control
Apr. 9	Diagnostic and therapeutic uses of radionuclides
Apr. 16	Applications of radionuclides (especially radioimmune assays)
Apr. 23	Experimental design
Apr. 30	Final Examination

Laboratory Experiments

1. Familiarization of basic detection equipment and determination of operating voltage of Geiger-Mueller detector
2. Preparation of a radioactive sample and determination of the half life of ^{99m}Tc
3. Determination of Resolving Time of a GM detector and Nuclear Counting Statistics
4. Efficiency Determinations and calibration of sources
5. Determination of operating voltage of NaI(Tl) detector
6. Determination of Integral and differential spectrum of ^{137}Cs & ^{60}Co
7. Determination of unknown gamma nuclides
8. Demonstration of multi-channel analyzer using a NaI(Tl) detector and an intrinsic germanium detector
9. Quality control determination of $\text{Na}^{99m}\text{TcO}_4$ and determination of precision using tuberculin syringes
10. Determination of distribution of ^{99m}Tc labeled product in a mouse
11. Tour of commercial radiopharmacy
12. Statistics of Nuclear Decay

General Policy:

1. All laboratory exercises must be completed by each student.
2. A laboratory report is to be submitted the week following the completion of the laboratory exercise.

SYLLABUS FOR ADVANCED RADIOPHARMACEUTICALS

Course No. P 450

Topics

Dr. Howard Stern

1. Kinetics of Mo-Tc generator systems including calculation of transient equilibrium factors
2. Theoretical basis of various radiopharmaceutical kits and technetium chemistry
3. Laboratory preparation of the following kits and mouse distribution studies:
 - a. Technetium-99m Sulfur Colloid (Liver imaging agents)
Test kits manufactured by Squibb, Mallinckrodt, Medipysics and Syncor
 - b. Skeletal Imaging:
Test kits manufactured by Squibb, New England Nuclear, Mallinckrodt and Procter & Gamble
 - c. Technetium-99m Aggregate Albumin
Test kits manufactured by Syncor, New England Nuclear, Medi+Physics and Mallinckrodt
 - d. Red Blood Cell Labeling:
Perform both "in vitro" and "in vivo" labeling of red blood cells
4. Techniques used for radioiodination studies
5. Review of appropriate Nuclear Regulatory Commission Regulatory guide as they pertain to medical programs and the practice of nuclear pharmacy
6. Quality Control procedures used for Radiopharmaceutical products and preparation of "floods" used for quality control in nuclear medicine
7. Review of sterile techniques required in radiopharmaceutical preparation

15 hours lecture

90 hours laboratory exercises

Summary of research elective topic

Students reviewed current literature to find suitable techniques for labeling compounds containing phosphate groups. Information was used to tag several important high energy phosphate compounds with Tc-99m. After successful tagging, distribution studies were performed in mice to determine organs of concentration. Comparisons were made between the newly synthesized compounds and several commercially available compounds.

Students were required to perform the tagging of the new compounds, perform quality control studies and do the distribution studies. These compounds will continue to be studied within the next year to determine whether or not the University should pursue patent applications for these new compounds.

Total number of hours required to perform the above work was 90 hours in the fall semester of 1983.

Research Professor: Elaine D. Mackowiak and Howard Stern