

**MPI Professional  
Service Centers**



a subsidiary of Medi-Physics, Inc.

MPI Professional Service Centers Inc.  
8312 State Road, Suite 3  
Philadelphia, PA 19136

(215) 624-8612

Date: August 1, 1988

030-29240

Jenny N. Johansen  
Nuclear Materials Safety - Section B  
Division of Radiation Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Region 1  
631 Park Avenue  
King of Prussia, PA 19046

RE: NRC Radioactive Materials License Number 37-27830-01  
(State of Pennsylvania Radioactive Materials Lic. # PA-515)  
(State of Pennsylvania Board of Pharmacy Lic. # PP-413186-L)

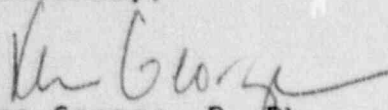
Dear Ms. Johansen:

On behalf of MPI Professional Service Centers, I would like to request that the above license be amended to include Thomas Donia as an authorized user. He is a graduate of the Philadelphia College of Pharmacy and Sciences, and has been a licensed pharmacist for approximately eight months. His state Board of Pharmacy license number is RP-0356882. Enclosed for your review, please find statements of training and experience for Mr. Donia.

Should you require additional information or clarification, please feel free to contact me at (215) 624-8612.

Thank you for your assistance in this matter.

Sincerely,

  
Ken George, R. Ph.  
Radiation Safety Officer

cc: Reading file  
License file

Log	Oct. 9
Remitter	
Check No.	13950
Amount	230
Fee Category	3C
Type of Fee	AMO
Date Check Rec'd.	10/11/88
Date Completed	10/11/88
By:	J. Kimberly

9001120079 881031  
REG1 LIC30 PDR  
37-27830-01

109577

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SEP 15 1988

# MPI Professional Service Centers

ROCHE

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MPI Professional Service Centers Inc.  
8312 State Road, Suite 3  
Philadelphia, PA 19136

(215) 624-8612

Date: August 1, 1988

Commonwealth of Pennsylvania  
Radioactive Materials Licensing  
Bureau of Radiation Protection  
Department of Environmental Resources  
PO Box 2063  
Harrisburg, PA 17120

Gentlemen:

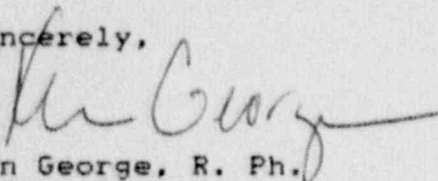
Please find the following enclosed:

- 1) Request of license amendment from MPI-PSC radiation safety officer
- 2) Documented Experience Handling Radioisotopes
- 3) Letter of successful completion of Nuclear Pharmacy course
- 4) Nuclear Pharmacy Certification Course Outline
- 5) Training received in basic radioisotope handling techniques
- 6) Nuclear Pharmacy Certification Course Exams

Should you require any additional information of clarification, please feel free to contact me at (215) 624-8612.

Your assistance in the matter is appreciated.

Sincerely,



Ken George, R. Ph.  
Pharmacy Manager



XAVIER UNIVERSITY OF LOUISIANA

college of pharmacy

7325 palmetto street  
new orleans, la 70125  
(504) 483-7424

July 20, 1988

Jenny N. Johansen  
Nuclear Materials Safety-Section B  
Division of Radiation Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Region 1  
631 Park Avenue  
King of Prussia, PA 19046

Dear Ms. Johansen,

We hereby certify that Mr. Thomas Donia has successfully completed studies in Nuclear Pharmacy through the Drexel Center of Xavier University of Louisiana.

<u>Course</u>	<u>Grade</u>
Lecture (50 hours)	High Pass
Laboratory (150 hours)	High Pass

This course is presented in keeping with NRC guidelines. The course content is enclosed for your review.

Lanny E. Foss, Ph. D.  
Associate Professor  
College of Pharmacy  
Xavier University of Louisiana

Anthony Edmond, R. Ph.  
Adjunct Instructor  
College of Pharmacy  
Xavier University of Louisiana

Janet E. Reuther, R. Ph.  
Adjunct Instructor  
College of Pharmacy  
Xavier University of Louisiana

Figure A-2

**DOCUMENTING EXPERIENCE HANDLING RADIOISOTOPES**  
 (Actual Use of Radioisotopes Under the Supervision of an Authorized User)

Name Tom Donia

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours)	TYPE OF USE (see key below)
Co-57	5mCi	MPI-PSC Philadelphia	80hrs	1,2,3,4,5
Ba-133	200uCi	"		1,2,4,5
Cs-137	200uCi	"		1,2,4,5
Tc-99m	200uCi	"		1,2,3,4,5,6
Tc-99m	14.0Ci	"	215hrs	1,3,4,5,6
Tl-201	50.0mCi	"	60hrs	"
Ga-67	50mCi	"	40hrs	"
Xe-133	3.5Ci	"	35hrs	"
I-131	75.0mCi	"	70hrs	"
I-123	3.0mCi	"	10hrs	"
In-111	3.0mCi	"	15hrs	"
P-32	10mCi	"	2hrs	"

Key for Type of Use

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performing related radiation surveys.
2. Calibrating dose calibrators, scintillation detectors, and survey meters.
3. Calculating, preparing, and calibrating patient doses, including properly using radiation shields.
4. Following appropriate internal control procedures to prevent mislabeling errors.
5. Learning emergency procedures to handle and contain spilled materials safely, including related procedures for decontamination, surveys, and wipe tests.
6. Eluting technetium-99m generator systems, assaying the eluate for technetium-99m and for molybdenum-99, and processing the eluate with reagent kits to prepare technetium-99m-labeled radiopharmaceuticals.



BUDDY ROEMER  
GOVERNOR

# State of Louisiana

DEPARTMENT OF ENVIRONMENTAL QUALITY

PAUL H. TEMPLET, Ph.D.  
SECRETARY

June 14, 1988

Lanny E. Foss, Ph.D.  
Xavier University of Louisiana  
College of Pharmacy  
7325 Palmetto Street  
New Orleans, Louisiana 70125

Dear Dr. Foss:

This is to acknowledge the Louisiana Nuclear Energy Division's review of the course outline submitted by Xavier University's College of Pharmacy. The course was designed to provide pharmacists with the required training in basic radioisotope handling techniques as part of the requirements for becoming an authorized user at a nuclear pharmacy.

The Division has found the course outline satisfactory and hereby approves the course to be presented as described. Records of students enrolled in the course and grades on the final exams must be maintained for inspection by the Division.

If we can provide further assistance in this matter, please do not hesitate to call our office.

Sincerely,

Jason R. Mason  
Nuclear Energy Division

cc: Anthony Edmond, R.Ph.

Xavier University Drexel CenterNuclear Pharmacy Certification Course

Lecture: (50 hours)

Course Content:

I. Course Introduction

II. History of Radiopharmacy

III. Radiation Physics

A. Atomic Structure

B. Nucleons

C. Nuclear transformations

1. alpha-decay

2. beta-decay

a. minus

b. plus (positron)

3. gamma-decay

4. electron capture

5. isomeric transition

D. Characteristics of radiations.

E. Radioactive decay

1. units

a. Curie, Becquerel (SI)

b. Roentgen

c. Rad [Radiation Absorbed Dose], Gray (SI)

d. Rem [Roentgen Equivalent Man], Sievert (SI)

2. half-life

3. equations

IV. Principles of Interaction of Radiation with Matter -  
Physical

A. Charged particles

1. alpha

2. beta

a. minus

b. plus

B. Electromagnetic radiation, gamma

C. Applications to radiation detection

V. Radiation Detection Instruments

A. Ion detectors

1. Electroscopes

2. Ionization chambers

3. Proportional counters

4. Geiger-Muller counters

B. Photon Detectors

1. Film

2. Scintillation Counters

VI. Principles of Interaction of Radiation with Matter -  
Chemical and Biological

- A. Molecules
  - 1. Water
  - 2. DNA
- B. Systems
  - 1. Cells
  - 2. Organ systems
  - 3. Whole body
- C. Effects of chronic radiation
- D. Special sensitivity of the fetus

VII. Modifiers of Biological Damage by Radiation

- A. Oxygen effect
- B. Temperature
- C. Metabolic rate
- D. Drugs
- E. Repair mechanisms

VIII. Delayed Effects of Radiation

- A. Premature aging
- B. Decreased life expectancy
- C. Growth retardation
- D. Carcinogenesis

~~IX. Radiation Protection - Factors~~

- A. Time
- B. Distance
- C. Shielding

X. Radiation Protection - Recommended Practices

XI. Radiation Protection - Maximum Permissible Dose

- A. Professionally exposed personnel
  - 1. whole body
  - 2. selected organ systems
- B. Other adults
- C. Children

XII. Monitoring of Personnel

- A. Devices
- B. Reporting

XIII. Radiopharmaceuticals

- A. "Ideal" radiopharmaceutical characteristics
- B. Available radionuclides
- C. Production of radionuclides
  - 1. Principles
  - 2. Reactors
  - 3. Cyclotrons / Accelerators
- D. Generators
- E. Clinically used radionuclides
  - 1. Currently in use

- a. nomenclature
- b. characteristics
- c. uses
- 2. Selected experimental agents
  - a. nomenclature
  - b. characteristics
  - c. proposed uses

#### XIU. Labelling of Chemicals with Radionuclides

- A. Principles
- B. Techniques
- C. Preparations in use

#### XV. Radiopharmacies - Regulatory Agencies

- A. Nuclear Regulatory Commission (NRC)
- B. Food and Drug Administration (FDA)
- C. Department of Transportation (DOT)
- D. State

#### XVI. Radiopharmacies - Facilities

- A. Facilities
  - 1. Types
  - 2. Designs
- B. Regulations regarding facilities

#### XVII. Radiopharmacies - Operation

- A. Handling of radiopharmaceuticals
- B. Regulations
  - 1. Procedures and record-keeping
    - a. incoming
    - b. on-site
    - c. outgoing
  - 2. Dispensing
  - 3. Quality control - Physicochemical
    - a. radionuclide purity
    - b. radiochemical purity
    - c. radioassay
    - d. pH / ionic strength
    - e. chemical purity
    - f. physical tests
  - 4. Quality control - Biological tests
    - a. sterility
    - b. pyrogenicity
  - 5. Waste management
    - a. procedures
    - b. record-keeping
  - 6. Personnel and facility monitoring
    - a. procedures
    - b. record-keeping



Laboratory: (150 hours)

- Experiment 1: Introduction and Safety
- Experiment 2: Half-life of Radioactive Decay
- Experiment 3: Characteristics of Radiations
- Experiment 4: Units of Radioactive Decay
- Experiment 5: Expiration Time of an Elution of  $^{99m}\text{Tc}$
- Experiment 6: Spectrometer - Introduction and Calibration
- Experiment 7: Spectrometer - Use
- Experiment 8: Dose Calibrator - Introduction and Calibration
- Experiment 9: Tests For Goodness of Fit
- Experiment 10: Survey Instrument - G-M Counter
- Experiment 11: Radiopharmacy Design
- Experiment 12: Radiopharmacy - Packages: Ordering and Handling
- Experiment 13: Quality Control
- Experiment 14: Dispensing Records
- Experiment 15: General Dispensing Procedures
- Experiment 16: Specific Dispensing Procedures and Practice
- Experiment 17: Personnel Monitoring
- Experiment 18: Use of Cautionary Signs

Figure A-1

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES\*

Name Tom Donia

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
Xavier University of Louisiana	June 6th - July 8th 1988	III A-D	48	48				
		III E	20			20		
		IV A-C	10	10				
		V A-B	26	26				
		VI A-D	20			20		
		VII A-E	3			3		
		VIII A-D	2			2		
		IX A-C	7		7			
		X	5		5			
		XI A-C	5		5			
		XII A-B	5		5			
		XIII A-E	14				14	
		XIV A-C	8				8	
		XV A-D	5		5			
		XVI A-B	2		2			
		XVII A-B1,2	7		7			
		XVII B3,4	8				8	
		XVIII B5,6	9		9			
			<b>TOTAL HOURS</b>	84	45	20	25	30

\*Note: Show a breakdown of hours by institutions, dates, and subjects. List each hour only once (i.e., under the most applicable subject category).

7-V

NAME \_\_\_\_\_

4 pgs. Be sure they are all here.

- I. (32 points) For each given atomic number:
- write the electronic configuration
  - identify the corresponding group number (or name) OR transitional metal
  - identify the corresponding ionic or covalent state
  - identify the number of coordinate covalent bonds in which the element is expected to act as donor or acceptor

A. #34 a. \_\_\_\_\_

b. \_\_\_\_\_ c. \_\_\_\_\_ d. \_\_\_\_\_

B. #30 a. \_\_\_\_\_

b. \_\_\_\_\_ c. \_\_\_\_\_ d. \_\_\_\_\_

C. #38 a. \_\_\_\_\_

b. \_\_\_\_\_ c. \_\_\_\_\_ d. \_\_\_\_\_

D. #54 a. \_\_\_\_\_

b. \_\_\_\_\_ c. \_\_\_\_\_ d. \_\_\_\_\_

- II. (9 points) Briefly define each of the following:

internal conversion

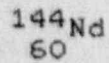
isomeric transition

rad

III. (12 points) Identify the relative characteristics of common nuclear radiations as low intermediate or high

	<u>alpha</u>	<u>beta</u>	<u>gamma</u>
speed	_____	_____	_____
mass	_____	_____	_____
ionizing power	_____	_____	_____
penetrating power	_____	_____	_____

IV. (24 points) For each given nuclide predict:  
a. one type of probable nuclear transformation (USE A VARIETY OF ANSWERS)  
b. identify the products of that nuclear transformation



V. (24 points) Calculate the answer to each of the following. SHOW YOUR WORK.

A. A sample of  $^{99m}\text{Tc}$  is needed for 4 pm administration to a patient at which time it is to have an activity of 5mCi. You are preparing it at 11 am. Calculate the activity needed in your 11 am prep. (half-life = 6.02 hours)

B. A therapeutic dose of  $^{131}\text{I}$  is being prepared for administration to a patient. You are preparing it at 4:30 am on Saturday; administration is to be accomplished at 10:30 am on Monday. The administered dose is to be 120mCi. Calculate the activity at time of preparation. (Half-life = 8 days.)

C. The initial activity of a dose of  $^{201}\text{Tl}$  is 2.5mCi at noon Monday. Calculate the activity at noon the following Wednesday. (half-life = 73.1 hours)

D. For a 5mCi sample of  $^{99m}\text{Tc}$  calculate:

a. activity of gigabecquerels

b. total mass of the  $^{99m}\text{Tc}$  in the sample

c. total number of  $^{99m}\text{Tc}$  atoms in the sample

NAME \_\_\_\_\_

3 pages. Be sure they are all here.

- I. For each named radiation detector
- a. provide a diagram
  - b. label the components of the diagram
  - c. write a brief description of the function of each component

- A. (20 points) electroscope

- a. provide a diagram
- b. label the components of the diagram
- c. write a brief description of the function of each component

B. (40 points) scintillation counter



- a. provide a diagram
- b. label the components of the diagram
- c. write a brief description of the function of each component

C. (40 points) G-M/ionization chamber/proportional counter

NAME \_\_\_\_\_

2 pages + 2 blanks

I. (20 points)

A. Compare and contrast somatic and genetic mutations.

B. Provide the graph of relative LET vs path length  
identify the Bragg peak  
discuss the relative LET's of an alpha particle of 3 Mev

## II. (80 points)

- A. Use reactions and written explanations to demonstrate:
- direct damage to biological molecules
  - indirect damage to biological molecules
  - the "chain" nature of free radical reactions
  - the damage liability associated with increased oxygen tension (up to normal)
  - the radioprotective effect of thiols.
- B. BRIEFLY discuss the probability of permanent damage to a cell when the radiation-damaged molecule is... (for 5 of the 7 types discussed in class).

NAME \_\_\_\_\_

4 pages

1> (20 points) Compare and contrast at least 5 of the properties of "ideal" diagnostic and "ideal" therapeutic radiopharmaceuticals.

II. (40 points) For 4 of the designated 7 "major" radiopharmaceuticals provide:

- a. identity
- b. decay mode
- c. energy of decay
- d. half-life
- e. use

III. (30 points) For 3 conceptually diverse reactions for introduction of a foreign radioactive label into a molecule provide a description of the reaction and a discussion of the advantages and/or disadvantages of this system.

IV. (10 points) Identify the species present in a chelated  $^{99m}\text{Tc}$  preparation. Describe how these are dealt with during quality control.

NAME \_\_\_\_\_

3 pages

I. (20 points) For each given additive used in radiopharmaceutical preparations identify the purpose for its inclusion in such preparations.

ascorbic acid \_\_\_\_\_

benzyl alcohol \_\_\_\_\_

gelatin \_\_\_\_\_

tris \_\_\_\_\_

tween 80 \_\_\_\_\_

II. (30 points) Name the five regulatory agencies described in class and list their major areas of concern.

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

4. \_\_\_\_\_

5. \_\_\_\_\_



III. (20 points)

A. Describe the purpose of Luer-Lok™ syringes and briefly describe one step which will insure that this purpose is not defeated.

B. List three groups or individuals to be notified if and incoming package of radioactive materials is received damaged and wet.

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

C. Describe what is meant by transportation index.

D. Describe what is meant by ALARA.

III. (30 points) For 3 of the 4 named radioisotopes provide the indicated information.

A.  $^{99m}\text{Tc}$  as pertechnetate

Explain why the GI tract is subjected to a dose approximately 10X that of the whole body.

Provide the explanation for pertechnetate usefulness in imaging brain lesions.

B.  $^{201}\text{Tl}$

Identify the mechanism for uptake into myocardial cells.

---

Identify the areas of the heart (healthy, ischemic, infarcted) which will be "hot":

shortly after administration \_\_\_\_\_

2-4 hours post administration \_\_\_\_\_

shortly after administration and stressful exercise

---

C.  $^{67}\text{Ga}$

Identify the endogenous substance on whose transport system this radioisotope hitchhikes.

---

State one of the hypothesized mechanisms for localization in areas of infection.

State one of the hypothesized mechanisms for localization in a tumor.

D.  $^{133}\text{Xe}$

Identify the normal route of administration.

---

Describe the significance of "cold" spots in a first-breath image.

Describe the significance of "hot" spots in a "washout" image.

109577

15 SEP 1988

OFFICIAL RECORD COPY ML 10

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

: (FOR LFMS USE)  
: INFORMATION FROM LTS  
: -----  
: PROGRAM CODE: 02500  
: STATUS CODE: 0  
: FEE CATEGORY: 3C  
: EXP. DATE: 19910731  
: FEE COMMENTS: -----  
: .....

LICENSE FEE TRANSMITTAL

A. REGION V

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: MPI PROFESSIONAL SERVICE CTRS. INC.  
RECEIVED DATE: 880915  
DOCKET NO: 3029240  
CONTROL NO.: 109577  
LICENSE NO.: 37-27830-01MD  
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: \$230  
CHECK NO.: 13959

3. COMMENTS

SIGNED \_\_\_\_\_  
DATE 9/23/88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1-T)

1. FEE CATEGORY AND AMOUNT: 3C \$ 230

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT \_\_\_\_\_  
RENEWAL \_\_\_\_\_  
LICENSE \_\_\_\_\_

3. OTHER \_\_\_\_\_  
\_\_\_\_\_

SIGNED \_\_\_\_\_  
DATE 10/11/88

A