SD 784-16

TELEPHONE (505) 345-3551

JUL 30 1984

Applicant
Check No. 1028 $110 / 33025 $120
Amount Fee Category
Type of Fee Amd
Date Check Rec'd 8/3/84
Received By CP

July 25, 1984

nuclear pharmacy incorporated
P.O. BOX 25141
ALBUQUERQUE, NEW MEXICO 87125

Bruce Mallett, Ph.D.
Chief of Material Licensing Section
Region III
U.S. Nuclear Regulatory Commisssion
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: License number 12-18044-01MD (Chicago)

Dear Dr. Mallett:

On behalf of Nuclear Pharmacy, Inc., I would like to request that the above license be amended to include the following:

1. Enclosed please find a copy of the revised floor plan. Area 1 was formerly a closet but will now be used as an area where radioactive materials may be used or stored. Area 2 indicates that a walkway has been created between work benches.

2. Please include Cathy A. Bach, Billy M. Ward, James Korb, Robert Grobinski, and Joseph Nacchio as authorized users. Statements of training and experience for Ms. Bach and Misters Ward and Korb have been submitted for your review. As Misters Grobinski and Nacchio already appear on an NRC license (copy included), their training and experience has not been included. **

See Amend. No. 27 wJa

3. Please increase our possession limit to the following:

BYPRODUCT MATERIAL	FORM	POSSESSION LIMIT
Molybdenum 99	Any approved Mo-99/Tc-99m generators	200 Curies
Technetium 99m	Any form listed in Groups I and II	200 Curies

Enclosed please find two (2) checks totaling the required amendment fee.

RECEIVED BY LFMB
Date 8/3/84
Log
By CP
Orig. to
Action Compl. CP

8510090072 850228
REG3 LIC30
12-18044-01MD PDR

RECEIVED
JUL 30 1984
REGION III

Control No. 77191

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

Thank you for your continued assistance.

Sincerely,

NUCLEAR PHARMACY, INC.

Steven Dessel, R.Ph.
Vice President of Professional and Regulatory Affairs

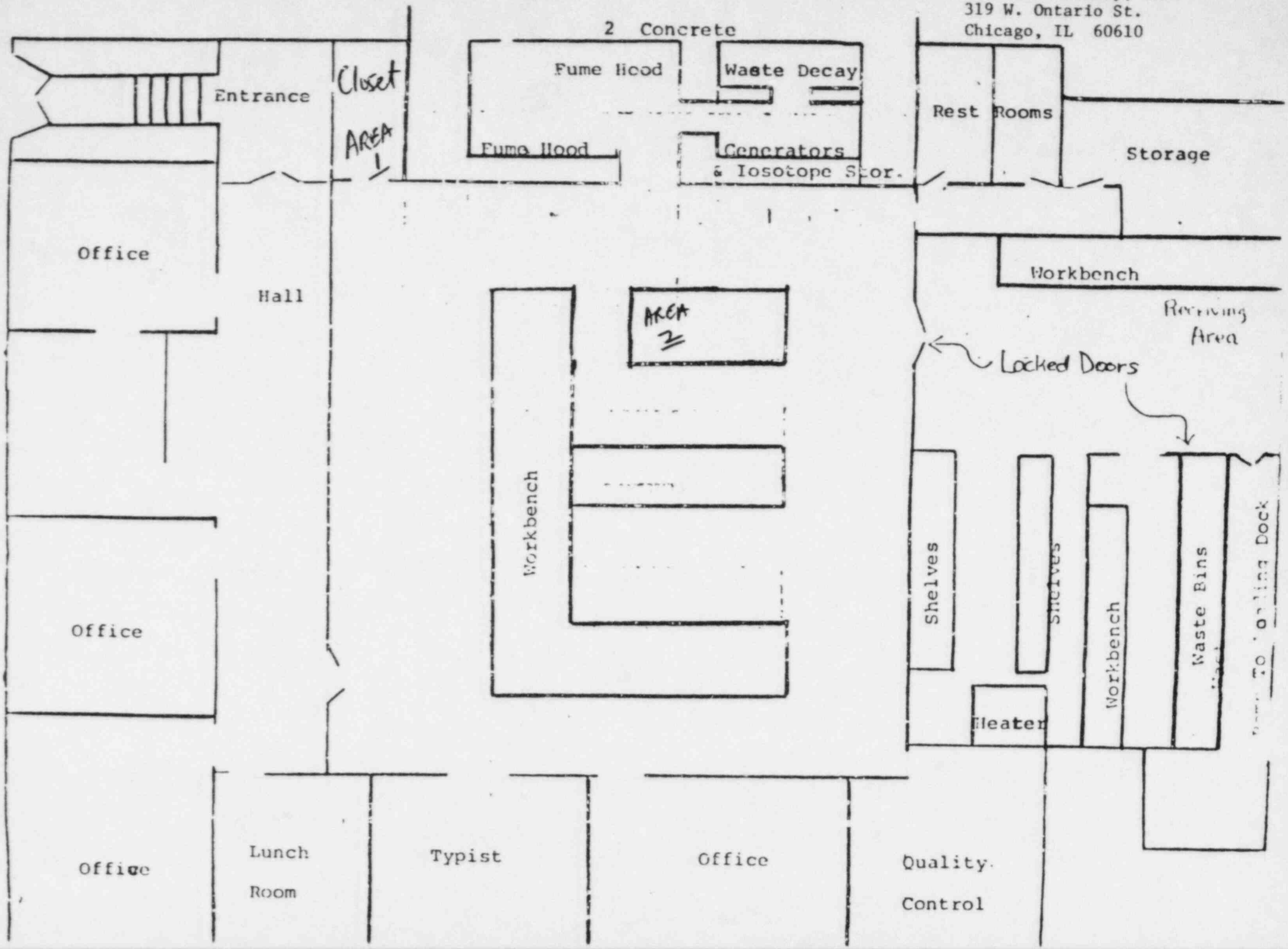
Enclosures

SD/gav

cc: Central File
Reading File
License Files
E. Fennell
B. Crescenzi

** In addition, please include Patricia Milligan as an authorized user. A copy of an amendment, on which she appears, has been included.

Nuclear Pharmacy, Inc.
319 W. Ontario St.
Chicago, IL 60610



NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Cathy A. Bach, R.Ph.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Ferris State College, College of Pharmacy Big Rapids, MI 49307 Spring 1980 Fall 1982 Winter 1983	90	
b. RADIATION PROTECTION	Ferris State College, College of Pharmacy Big Rapids, MI 49307 Spring 1980 Spring 1982 Winter 1983	45	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Ferris State College, College of Pharmacy Big Rapids, MI 49307 Spring 1980 Fall 1982 Winter 1983	25	
d. RADIATION BIOLOGY	Ferris State College, College of Pharmacy Big Rapids, MI 49307 Fall 1982	25	
e. RADIOPHARMACEUTICAL CHEMISTRY	Ferris State College, College of Pharmacy Big Rapids, MI 49307 Winter 1983	35	

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 the attached sheets from Ferris State College and Nuclear Pharmacy, Inc.		

F.S.C. NUCLEAR PHARMACY

CONTENT (HOURS) / COURSE	CREDIT	PHYSICS AND INSTRUMENTS	PROTECTION	BIOLOGY	MATH	CHEM	TOTAL
1. PHN-306 Radioisotopes	2	25	10		15		50
2. PHN-308 Radioisotopes Lab.	1						
3. PHN-360 Radiation Biology	3			25	5		30
4. PHN-380 Radiation Health Physics	3		30				30
5. PHN-460 Radiopharmaceutics	3	50					50
6. PHN-470 Radiopharmaceuticals	3					30	30
7. PHN-520 Nuclear Prescriptions Laboratory	1	15	5		5	5	30
Totals	16	90*	45*	25	25	35	220
NRC - Requirements (Delmedico)		85	45	20	20	30	200
NRC Guide Appendix A 10.8 (10/1/80)		100	30	20	20	30	200

*10 hours of Health Physics (Protection) covers Physics and Instrumentation of Protection

David W. Bath, R.Ph., Ph.D.
Associate Professor of Nuclear Pharmacy

Pharmacy, Nuclear

PHN 304. Introduction to Nuclear Pharmacy. 1 Cr.
Principles of ionizing radiation, instrumentation and health physics concepts pertinent to radiopharmaceuticals and nuclear pharmacy. Prerequisite: CHM 110 or CHM 123 or consent of instructor. (1+0)

PHN 306. Radioisotopes. 2 Cr.
Properties and physics of ionizing radiation along with the characteristics, detection and uses of radionuclides are discussed. Biological and chemical effects of radiation, diagnostic and therapeutic uses of radionuclides and the mathematical concepts involved are emphasized. Prerequisites: CHM 110 or CHM 123 or consent of instructor. (2+0)

PHN 308. Radioisotopes Laboratory. 1 Cr.
Acquaints the student with the detection systems for measuring ionizing radiation, the errors, standardization and radiotracer methodology. Health physics and the mathematics of radiotracer applications are stressed. Prerequisites: PHN 303 or consent of instructor. (0+3)

PHN 350. Radioimmunoassays. 3 Cr.
A study of radioimmunoassays and competitive binding assays. After a study of theory and the production of reagents, the final kits are used for assays on various drugs and hormones. (2+3)

PHN 360. Radiation Biology. 3 Cr.
Measurement of radiation, dosimetry of radionuclides and interactions of radiations with living organisms are discussed. Radiation effects on genetic material, nucleus, cytoplasm, histology, and total organism are covered. Bone marrow, gastrointestinal and central nervous system syndromes, delayed and embryonic effects are discussed. Prerequisites: CHM 110 or CHM 123 and BIO 205 or equivalent or consent of instructor. (3+0)

PHN 390. Radiation Health Physics. 3 Cr.
Federal and state regulation, radiation safety, monitoring and calibration of equipment. Shield design, thickness calculations, radiation dosimetry and proper safety habits are emphasized. Prerequisites: PHN 306, PHN 308. (3+0)

PHN 460. Radiopharmaceuticals. 3 Cr.
Design, preparation, quality assurance, dispensing, calculation and record keeping of radiopharmaceuticals. Prerequisites: PHN 306, PHN 308. (2+3)

PHN 470. Radiopharmaceuticals. 3 Cr.
Pharmacology preparation, quality control, biological behavior and uses of radiopharmaceuticals used in nuclear medicine. Prerequisites: PHN 306, PHN 308. (3+0)

PHN 520. Nuclear Prescription Laboratory. 1 Cr.
Prepares the student for actual practice. Includes calibration of instruments. Quality control including radiochemical purity, radionuclidic and ammonium breakthrough, radiochemical purity, pH, particle size, dosage, sterility and apyrogenicity. Prerequisites: PHN 460, PHN 470 (0+3).

PHN 595. Special Problems in Nuclear Pharmacy. 1-4 Cr.
Student will select a topic for independent investigation. An examination paper will be required. Prerequisite: Consent of instructor.

EXPERIENCE WITH RADIOISOTOPES AT F.S.C.

PHN-308 LAB - 30 Hours

Isotope	Maximum Amount
1. P-32	1 mci
2. I-131	1 mci
3. C-14	10 uci
4. H-3	10 uci
5. Co-57	10 uci
6. Na-22	10 uci
7. Co-60	1 uci

PHN-520 and PHN-460 Lab - 60 Hours

1. Tc-99 m	220 mci
2. Mo-99	220 mci
3. I-131	10 mci
4. Co-137	125 uci
5. Co-60	125 uci
6. Co-57	900 uci

EXPERIENCE WITH RADIATION

Cathy A. Bach, R.Ph.

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
Mo-99/Tc-99m Generators	8Ci	Nuclear Pharmacy, Inc. Chicago, IL	5-23-84 to present (500 hours)	-Compounding and dispensing for patients and hospitals on a prescription order
Tc-99m labeled products	500mCi/product	"	"	"
I-131	100mCi	"	"	"
I-123	5mCi	"	"	"
Xe-133	100mCi	"	"	"
Tl-201	15mCi	"	"	"
Ga-67	15mCi	"	"	"
Co-57 Ba-133 Cs-137	As Sealed Sources	"	"	"

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Billy M. Ward	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

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		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Purdue University, College of Pharmacy Spring 1982 Fall 1982 Spring 1983 Fall 1983	83	
b. RADIATION PROTECTION	Purdue University, College of Pharmacy Spring 1982 Fall 1982 Spring 1983 Fall 1983	40	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Purdue University, College of Pharmacy Fall 1982 Spring 1983 Fall 1983	24	
d. RADIATION BIOLOGY	Purdue University, College of Pharmacy Spring 1982 Fall 1982 Spring 1983	20	
e. RADIOPHARMACEUTICAL CHEMISTRY	Purdue University, College of Pharmacy Spring 1982 Fall 1982 Spring 1983	50	

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 the attached sheets		

EXPERIENCE WITH RADIATION

Billy M. Ward

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
Mo 99/Tc 99m Generators	3 Ci	Nuclear Pharmacy, Inc. - Las Vegas, NV - Harrisburg, PA	5/83 - 9/83 (600 hours) 5/84 - present (200 hours)	Compounding and dispensing for patients and hospitals on a prescription order
Tc 99m labelled products	500mCi/ product	"	"	"
Xenon 133	1 Ci	"	"	"
Iodine 131	100 mCi	"	"	"
Iodine 123	1 mCi	"	"	"
Selenium 75	300 uCi	"	"	"
Thallium 201	20 mCi	"	"	"
Yb 169 DTPA	10 mCi	"	"	"
P-32	50 mCi	"	"	"
Co-57 Ba-133 Cs-137	As Sealed Sources	"	"	"
Gallium 67	40 mCi	"	"	"

INTERNSHIP IN NUCLEAR PHARMACY

I. INTRODUCTION

The objective of the internship is to provide a supervised experience in the various aspects of nuclear pharmacy practice. The student will participate in those functions necessary for the preparation and provision of radiopharmaceutical products for nuclear medicine. The student will become familiar with clinical nuclear pharmacy considerations as well as clinical nuclear medicine procedures and problems. A high degree of practice proficiency will be expected upon completion of the internship.

II. METHODOLOGY

A. Principles of Practice Experience

1. Nuclear pharmacy site

The nuclear pharmacy involved in the practice experience will be licensed and registered by a state board of pharmacy. The manager of the nuclear pharmacy will also be registered by the state board of pharmacy in the state in which he/she practices. He/she will be recognized by the Purdue University School of Pharmacy and Pharmacal Sciences faculty for his participation in the program. The nuclear pharmacy practice site will be reviewed by a member of the faculty in order to approve the site for the program.

2. Student participation

Students will be selected from those who have completed the three courses pertaining to nuclear pharmacy (BNUC 412, BNUC 414, BNUC 530). Those desiring to participate will be interviewed by a School of Pharmacy and Pharmacal Sciences faculty member and by an individual representing the nuclear pharmacy experience site.

3. Orientation

The student will be introduced to personnel and made aware of their responsibilities. The student will tour the nuclear pharmacy in order to identify the location of equipment, supplies, specialized work areas, and waste disposal areas. The nuclear pharmacist will conduct an orientation interview with the student to provide information concerning the rules and regulations under which the nuclear pharmacy functions.

B. Nuclear Pharmacy Services

The student will gain experience in all aspects of nuclear pharmacy services and functions in order to develop a thorough knowledge of such services and become capable of functioning proficiently.

1. Radiopharmaceutical orders

The student will learn the methods of receiving an order for a radiopharmaceutical. The student will learn to determine the daily needs of the nuclear pharmacy and the appropriate scheduling of orders.

2. Radiopharmaceutical preparation

Proper generator elution techniques to insure optimum radioactive isotope concentrations, preparation of radiopharmaceuticals, and dispensing of unit doses will be included in this area of practice experience. The student will become capable of coordinating the preparation of radiopharmaceuticals so as to maximize the efficient use of time, equipment, and materials.

3. Quality control of radiopharmaceuticals and nuclear pharmacy instruments

The student will become proficient in the verification of the radiochemical purity, radionuclidic purity, chemical purity, and the pharmaceutical quality of radiopharmaceuticals. The student will become capable of completing the quality control procedures established by the nuclear pharmacy. In addition, determination of the precision of nuclear pharmacy instrumentation will be covered in this aspect of the practice experience.

4. Unit dose preparation of radiopharmaceuticals for delivery to hospitals

The student will learn the process of drug delivery from the preparation, labeling, and packaging of the radiopharmaceutical to the administration to the patient. The student should complete a delivery of the doses to a hospital with the regular delivery personnel.

5. Record keeping

The student will become familiar with the record keeping system of the nuclear pharmacy. This will include the maintenance of appropriate daily records pertaining to quality control of radiopharmaceuticals and instrumentation, patient doses, ordering, receipt, storage, preparation, health physics, radioactive waste disposal and business aspects of the nuclear pharmacy.

6. Ordering methods

The student will learn the ordering procedures and guidelines utilized within the nuclear pharmacy and participate in the ordering, receiving, checking, pricing, and stocking of supplies.

7. Professional communication

The student will participate in discussions with health professionals contacted by the nuclear pharmacy. Selection of radiopharmaceuticals, quality control assurance in relation to abnormal clinical information are examples of beneficial communication experiences.

8. Altered radiopharmaceutical localization

The student will become knowledgeable of patient, drug and other factors interfering with radiopharmaceutical localization and pharmacokinetics. The student will participate in the prevention and/or explanation of alterations in radiopharmaceutical biodistribution. The student will become proficient in the retrieval and assessment of literature sources pertinent to clinical nuclear pharmacy services.

9. Education

The student will participate in patient information services provided by the nuclear pharmacy. The student will prepare pertinent drug and other information for nuclear medicine and hospital personnel.

C. Managerial Procedures

1. Legal aspects of nuclear pharmacy establishment

The student will learn the legal requirements and policies of the various institutions that play an active part in the establishment of the nuclear pharmacy, i.e. F.D.A., N.R.C., D.O.T. and the state board of pharmacy.

2. Patient and hospital charging procedures

The student should learn the method of determining the appropriate charge for nuclear pharmacy items as well as know the mechanism of billing the hospitals and the normal procedures for proper payment. Introduction to the general business aspect of providing nuclear pharmacy services to hospitals and other clients should be included.

3. Administrative aspects

Personnel management philosophy, budgeting procedures and allocation, relationship with the board of directors of the company, and general administration of the nuclear pharmacy practice at the respective site can be included.

D. Health Physics

1. The student will participate in routine health physics monitoring procedures for the nuclear pharmacy. This will include area monitoring, wipe testing and record keeping.

2. The student will learn the procedures used by the nuclear pharmacy to shield radioactive material in storage, compounding, dispensing and waste areas, as well as techniques used to minimize radiation exposure to personnel.

3. The student will become familiar with nuclear pharmacy procedures for personnel monitoring, record keeping and handling of accidental contamination.

E. Clinical Nuclear Medicine

If possible, the student should observe nuclear medicine clinical procedures to gain an understanding of the procedures, nuclear medicine instrumentation, and the role of health professionals in a nuclear medicine unit. Also, attendance at interpretation sessions would provide knowledge of expected results, factors interfering with the procedure and the interrelationship between nuclear medicine and other diagnostic disciplines.

Course Title: Practicum in Nuclear Pharmacy

Course Number: BNUC 416

Course Description: BNUC 416 Practicum in Nuclear Pharmacy, SS. Cr. 1. Prerequisite: BNUC 414 or consent of instructor. A structured, supervised practice experience in nuclear pharmacy. Students will participate in the preparation and provision of radiopharmaceuticals for nuclear medicine. Emphasis will be placed upon fundamental concepts of nuclear physics, instrumentation, health physics, and radiopharmaceutical science as applied to pharmacy practice. Professor Shaw.

Number of Credits: 1

Class Format: Students will be assigned to a licensed nuclear pharmacy under the direct supervision of a registered pharmacist. The nuclear pharmacy site will be determined by a representative of the pharmacy in cooperation with a member of the faculty. The nuclear pharmacist and student will be provided with material describing course objectives and areas of emphasis. Student performance will be evaluated by examination, communication with the pharmacist, an activity log, and a brief written report due one week prior to termination of the semester. Grading will be on a pass/no pass basis.

Prerequisites: BNUC 414 or consent of instructor.

Instructor in Charge: Stanley M. Shaw

Course Objectives: To provide practical experience leading to competence in the procurement, preparation, and dispensing of radiopharmaceuticals as well as other professional pharmacy services common to nuclear pharmacy practice.

Text: Practical Nuclear Pharmacy by Trent Phan and Richard Wasnich

Recommended Course Outline: Based upon one credit hour representing 45 hours of laboratory experience.

Time, Hours	Topic
3	Radiopharmaceutical orders

The student will learn the methods of receiving an order for a radiopharmaceutical. The student will learn to determine the daily needs of the nuclear pharmacy and the appropriate scheduling of orders.

Time, Hours	Topic
4	Radiopharmaceutical preparation Proper generator elution techniques to insure optimum radioactive isotope concentrations, preparation of radiopharmaceuticals, and dispensing of unit doses will be included in this area of practice experience. The student will become capable of coordinating the preparation of radiopharmaceuticals so as to maximize the efficient use of time, equipment, and materials.
4	Quality control of radiopharmaceuticals and nuclear pharmacy instruments The student will become proficient in the verification of the radiochemical purity, radionuclidic purity, chemical purity, and the pharmaceutical quality of radiopharmaceuticals. The student will become capable of completing the quality control procedures established by the nuclear pharmacy. In addition, determination of the precision of nuclear pharmacy instrumentation will be covered in this aspect of the practice experience.
4	Unit dose preparation of radiopharmaceuticals for delivery to hospitals The student will learn the process of drug delivery from the preparation, labeling, and packaging of the radiopharmaceutical to the administration to the patient. The student should complete a delivery of the doses to a hospital with the regular delivery personnel.
4	Record keeping The student will become familiar with the record keeping system of the nuclear pharmacy. This will include the maintenance of appropriate daily records pertaining to quality control of radiopharmaceuticals and instrumentation, patient doses, ordering, receipt, storage, preparation, healt physics, radioactive waste disposal and business aspects of the nuclear pharmacy.
3	Ordering methods The student will learn the ordering procedures and guidelines utilized within the nuclear pharmacy and participate in the ordering, receiving, checking, pricing, and stocking of supplies.

2 Professional communication

The student will participate in discussions with health professionals contacted by the nuclear pharmacy. Selection of radiopharmaceuticals, quality control assurance in relation to abnormal clinical information are examples of beneficial communication experiences.

1 Altered radiopharmaceutical localization

The student will become knowledgeable of patient, drug and other factors interfering with radiopharmaceutical localization and pharmacokinetics. The student will participate in the prevention and/or explanation of alterations in radiopharmaceutical biodistribution. The student will become proficient in the retrieval and assessment of literature sources pertinent to clinical nuclear pharmacy services.

1 Education

The student will participate in patient information services provided by the nuclear pharmacy. The student will prepare pertinent drug and other information for nuclear medicine and hospital personnel.

MANAGERIAL PROCEDURES

1 Legal aspects of nuclear pharmacy establishment

The student will learn the legal requirements and policies of the various institutions that play an active part in the establishment of the nuclear pharmacy, i.e. F.D.A., N.R.C., D.O.T. and the state board of pharmacy.

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1 Administrative aspects

Personnel management philosophy, budgeting procedures and allocation, relationship with the board of directors of the company, and general administration of the nuclear pharmacy practice at the respective site can be included.

HEALTH PHYSICS

5	The student will participate in routine health physics monitoring procedures for the nuclear pharmacy. This will include area monitoring, wipe testing and record keeping.
5	The student will learn the procedures used by the nuclear pharmacy to shield radioactive material in storage, compounding, dispensing and waste areas, as well as techniques used to minimize radiation exposure to personnel.
3	The student will become familiar with nuclear pharmacy procedures for personnel monitoring, record keeping and handling of accidental contamination.

CLINICAL NUCLEAR MEDICINE

3	If possible, the student should observe nuclear medicine clinical procedures to gain an understanding of the procedures, nuclear medicine instrumentation, and the role of health professionals in a nuclear medicine unit. Also, attendance at interpretation sessions would provide knowledge of expected results, factors interfering with the procedure and the interrelationship between nuclear medicine and other diagnostic disciplines.

Continued

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
In-113m	10 µCi	Purdue University	3 hours	Laboratory experience
Cs-137	1 µCi	"	20 hours	"
P-32	1 mCi	"	6 hours	"
Co-60	1 mCi	"	1 hour	"
Ba-137m	1 µCi	"	3 hours	"
Sn-113	10 µCi	"	3 hours	"
Tc-99m	1 mCi	"	12 hours	"
Tc-99m	1-5 mCi	"	30 hours	"

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
James Korb	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

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
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		See the attached sheets		

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name James Korb

Location of Training	Date(s) of Attendance	Course Title if Applicable	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	
				A	B	A	B	A	B	A	B	A	
Purdue University	Spring 1982	Nuclear Pharmacy BNUC 412	47	25	-	2	-	-	-	7		13	
	Fall 1982	Nuclear Pharmacy Laboratory BNUC 414	45	20		6		6		3		10	
	Spring 1983	Applied Nuclear Pharmacy BNUC 530	77	18		12		10		10		27	
	Fall 1983	Special Projects (Research) BNUC 490	48	20		20		8					
*Column "A" refers to Lecture/Laboratory Course Column "B" refers to Supervised Laboratory Experience			217 TOTAL HOURS	83	-	40	-	24	-	20	-	50	-

EXPERIENCE WITH RADIATION

James Korb

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Tc 99m labelled products	500mCi/ product	"	"	"
Xenon 133	1 Ci	"	"	"
Iodine 131	100 mCi	"	"	"
Iodine 123	1 mCi	"	"	"
Selenium 75	300 uCi	"	"	"
Thallium 201	20 mCi	"	"	"
Yb 169 DTPA	10 mCi	"	"	"
P-32	50 mCi	"	"	"
Co-57 Ba-133 Cs-137	As Sealed Sources	"	"	"
Gallium 67	40 mCi	"	"	"

INTERNSHIP IN NUCLEAR PHARMACY

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The student will learn the ordering procedures and guidelines utilized within the nuclear pharmacy and participate in the ordering, receiving, checking, pricing, and stocking of supplies.

7. Professional communication

The student will participate in discussions with health professionals contacted by the nuclear pharmacy. Selection of radiopharmaceuticals, quality control assurance in relation to abnormal clinical information are examples of beneficial communication experiences.

8. Altered radiopharmaceutical localization

The student will become knowledgeable of patient, drug and other factors interfering with radiopharmaceutical localization and pharmacokinetics. The student will participate in the prevention and/or explanation of alterations in radiopharmaceutical biodistribution. The student will become proficient in the retrieval and assessment of literature sources pertinent to clinical nuclear pharmacy services.

9. Education

The student will participate in patient information services provided by the nuclear pharmacy. The student will prepare pertinent drug and other information for nuclear medicine and hospital personnel.

C. Managerial Procedures

1. Legal aspects of nuclear pharmacy establishment

The student will learn the legal requirements and policies of the various institutions that play an active part in the establishment of the nuclear pharmacy, i.e. F.D.A., N.R.C., D.O.T. and the state board of pharmacy.

2. Patient and hospital charging procedures

The student should learn the method of determining the appropriate charge for nuclear pharmacy items as well as know the mechanism of billing the hospitals and the normal procedures for proper payment. Introduction to the general business aspect of providing nuclear pharmacy services to hospitals and other clients should be included.

3. Administrative aspects

Personnel management philosophy, budgeting procedures and allocation, relationship with the board of directors of the company, and general administration of the nuclear pharmacy practice at the respective site can be included.

D. Health Physics

1. The student will participate in routine health physics monitoring procedures for the nuclear pharmacy. This will include area monitoring, wipe testing and record keeping.

2. The student will learn the procedures used by the nuclear pharmacy to shield radioactive material in storage, compounding, dispensing and waste areas, as well as techniques used to minimize radiation exposure to personnel.

3. The student will become familiar with nuclear pharmacy procedures for personnel monitoring, record keeping and handling of accidental contamination.

E. Clinical Nuclear Medicine

If possible, the student should observe nuclear medicine clinical procedures to gain an understanding of the procedures, nuclear medicine instrumentation, and the role of health professionals in a nuclear medicine unit. Also, attendance at interpretation sessions would provide knowledge of expected results, factors interfering with the procedure and the interrelationship between nuclear medicine and other diagnostic disciplines.

Course Title: Practicum in Nuclear Pharmacy

Course Number: BNUC 416

Course Description: BNUC 416 Practicum in Nuclear Pharmacy, SS. Cr. 1. Prerequisite: BNUC 414 or consent of instructor. A structured, supervised practice experience in nuclear pharmacy. Students will participate in the preparation and provision of radiopharmaceuticals for nuclear medicine. Emphasis will be placed upon fundamental concepts of nuclear physics, instrumentation, health physics, and radiopharmaceutical science as applied to pharmacy practice. Professor Shaw.

Number of Credits: 1

Class Format: Students will be assigned to a licensed nuclear pharmacy under the direct supervision of a registered pharmacist. The nuclear pharmacy site will be determined by a representative of the pharmacy in cooperation with a member of the faculty. The nuclear pharmacist and student will be provided with material describing course objectives and areas of emphasis. Student performance will be evaluated by examination, communication with the pharmacist, a activity log, and a brief written report due one week prior to termination of the semester. Grading will be on a pass/no pass basis.

Prerequisites: BNUC 414 or consent of instructor.

Instructor in Charge: Stanley M. Shaw

Course Objectives: To provide practical experience leading to competence in the procurement, preparation, and dispensing of radiopharmaceuticals as well as other professional pharmacy services common to nuclear pharmacy practice.

Text: Practical Nuclear Pharmacy by Trent Phan and Richard Wasnich

Recommended Course Outline: Based upon one credit hour representing 45 hours of laboratory experience.

Time, Hours	Topic
3	Radiopharmaceutical orders

The student will learn the methods of receiving an order for a radiopharmaceutical. The student will learn to determine the daily needs of the nuclear pharmacy and the appropriate scheduling of orders.

Time, Hours	Topic
4	Radiopharmaceutical preparation Proper generator elution techniques to insure optimum radioactive isotope concentrations, preparation of radiopharmaceuticals, and dispensing of unit doses will be included in this area of practice experience. The student will become capable of coordinating the preparation of radiopharmaceuticals so as to maximize the efficient use of time, equipment, and materials.
4	Quality control of radiopharmaceuticals and nuclear pharmacy instruments The student will become proficient in the verification of the radiochemical purity, radionuclidic purity, chemical purity, and the pharmaceutical quality of radiopharmaceuticals. The student will become capable of completing the quality control procedures established by the nuclear pharmacy. In addition, determination of the precision of nuclear pharmacy instrumentation will be covered in this aspect of the practice experience.
4	Unit dose preparation of radiopharmaceuticals for delivery to hospitals The student will learn the process of drug delivery from the preparation, labeling, and packaging of the radiopharmaceutical to the administration to the patient. The student should complete a delivery of the doses to a hospital with the regular delivery personnel.
4	Record keeping The student will become familiar with the record keeping system of the nuclear pharmacy. This will include the maintenance of appropriate daily records pertaining to quality control of radiopharmaceuticals and instrumentation, patient doses, ordering, receipt, storage, preparation, heal physics, radioactive waste disposal and business aspects of the nuclear pharmacy.
3	Ordering methods The student will learn the ordering procedures and guidelines utilized within the nuclear pharmacy and participate in the ordering, receiving, checking, pricing, and stocking of supplies.

2 Professional communication

The student will participate in discussions with health professionals contacted by the nuclear pharmacy. Selection of radiopharmaceuticals, quality control assurance in relation to abnormal clinical information are examples of beneficial communication experiences.

1 Altered radiopharmaceutical localization

The student will become knowledgeable of patient, drug and other factors interfering with radiopharmaceutical localization and pharmacokinetics. The student will participate in the prevention and/or explanation of alterations in radiopharmaceutical biodistribution. The student will become proficient in the retrieval and assessment of literature sources pertinent to clinical nuclear pharmacy services.

1 Education

The student will participate in patient information services provided by the nuclear pharmacy. The student will prepare pertinent drug and other information for nuclear medicine and hospital personnel.

MANAGERIAL PROCEDURES

1 Legal aspects of nuclear pharmacy establishment

The student will learn the legal requirements and policies of the various institutions that play an active part in the establishment of the nuclear pharmacy, i.e. F.D.A., N.R.C., D.O.T. and the state board of pharmacy.

1 Patient and hospital charging procedures

The student should learn the method of determining the appropriate charge for nuclear pharmacy items as well as know the mechanism of billing the hospitals and the normal procedures for proper payment. Introduction to the general business aspect of providing nuclear pharmacy services to hospitals and other clients should be included.

1 Administrative aspects

Personnel management philosophy, budgeting procedures and allocation, relationship with the board of directors of the company, and general administration of the nuclear pharmacy practice at the respective site can be included.

HEALTH PHYSICS

5 The student will participate in routine health physics monitoring procedures for the nuclear pharmacy. This will include area monitoring, wipe testing and record keeping.

5 The student will learn the procedures used by the nuclear pharmacy to shield radioactive material in storage, compounding, dispensing and waste areas, as well as techniques used to minimize radiation exposure to personnel.

3 The student will become familiar with nuclear pharmacy procedures for personnel monitoring, record keeping and handling of accidental contamination.

CLINICAL NUCLEAR MEDICINE

3 If possible, the student should observe nuclear medicine clinical procedures to gain an understanding of the procedures, nuclear medicine instrumentation, and the role of health professionals in a nuclear medicine unit. Also, attendance at interpretation sessions would provide knowledge of expected results, factors interfering with the procedure and the interrelationship between nuclear medicine and other diagnostic disciplines.

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
In-113m	10 µCi	Purdue University	3 hours	Laboratory experience
Cs-137	1 µCi	"	20 hours	"
P-32	1 mCi	"	6 hours	"
Co-60	1 mCi	"	1 hour	"
Ba-137m	1 µCi	"	3 hours	"
Sn-113	10 µCi	"	3 hours	"
Tc-99m	1 mCi	"	12 hours	"
Tc-99m	1-5 mCi	"	30 hours	"

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 1 OF 1 PAGES

License number
37-18461-01MD

Docket or Reference number
030-15125

Amendment No. 23

Nuclear Pharmacy, Inc.
dba Elfreth's Alley Apothecary
31-33 North 2nd Street
Philadelphia, Pennsylvania 19106

In accordance with letter dated May 16, 1984, License Number 37-18461-01MD is amended as follows:

Conditions 12. and 24. are amended to read:

12. A. Licensed material shall be used by, or under the supervision of, Robert L. Sanchez, Nunzio P. DeSantis, Garry R. Sullivan, Barry Crescenzi, Elaine M. Tomasulo, Carl M. DeJuliis, Steven Dessel, Arthur Solomon, David Ward, Roy Storey, William Guthrey, George S. Gillard, Robert Goodloe, Ken Barat, Joan Goodloe, Jon M. Reavis, Michael J. Kelly, Gregory Doerr, Randy A. Asmus, Frank A. Schweitzer, James Pancy, Herbert Jan, James F. Diamond, David McLeland, Dominique Smith, Patricia Horvat, Edmond Fennel, Cynthia Strobel, Gary Klockow, John Manzi, Gregory Snyder, Cher Conklin-Reed, R. Ph., Jeffery K. Steffey, Steve Robertson, Steve Bruski, Robert Grobinski or Joseph Nacchio.

B. At least one individual named in Condition 12.A shall be physically present at the authorized place of use whenever licensed material is being used.

C. The Radiation Protection Officer for the activities authorized by this license is Frank A. Schweitzer.

24. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in letter received May 22, 1981; application dated July 15, 1981; letters dated July 12, 1982, October 15, 1982, November 30, 1982, and May 24, 1983; letters and attachments dated May 13, 1983, and September 2, 1983; letters dated September 13, 1983, November 16, 1983, December 9, 1983; letter with attachments dated February 21, 1984, and letter with attachments dated May 16, 1984. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Date JUN 18 1984

By Original Signed By:
John D. Glenn

Nuclear Materials and Safeguards Branch
Region I
King of Prussia, Pennsylvania 19406

Dupe of
~~8404020160~~

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PAGE 1 OF 1 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 14-19990-01MD

Docket or Reference number

Amendment No. 05

Nuclear Pharmacy, Inc.
1221 Center Street, Suite 9
Des Moines, IA 50309

In accordance with letter dated March 1, 1984, License Number 14-19990-01MD is amended as follows:

Condition 12. is amended to read:

12. A. Licensed material shall be used by, or under the supervision of, Robert L. Sanchez, Arthur C. Solomon, William Guthrey, Nunzio M. De Santis, Steven Dessel, James M. Fulton, George S. Gillard, Carl M. DeJuliis, Gary R. Sullivan, David Ward, Roy Storey, Ken Barat, Edmond Fennel, Gregory Doerr, Randy A. Asmus, Dominique Smith, Elaine Tomasulo, Frank Schweitzer, David McLeland, Patricia Horvat, James Pancy, James Diamond, Barry Crescenzi, Herbert Jan, Cynthia Strobel, Gary Klockow, Jeffrey K. Steffey, John Manzi, Steve Robertson, Steve Bruski, or Patricia Milligan.

B. At least one individual named in Condition No. 12.A shall be physically present at the authorized place of use whenever licensed material is being used.

C. The Radiation Protection Officer for the activities authorized by this license is Edmond Fennel.

For the U.S. Nuclear Regulatory Commission

Original Signed
By Bruce S. Mallett
Materials Licensing Section, Region III

Date April 24, 1984 Dupe

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Control No. 77191 COPY 5

U.S. NUCLEAR REGULATORY COMMISSION

[D]ATA INPUT—INDUSTRIAL, MEDICAL, SOURCE/SPECIAL NUCLEAR

A. TYPE OF ACTION AND IDENTIFICATION CODES

[L]ICENSE		AMENDMENT TO RENEW LICENSE		AMENDMENT TO TERMINATE	X	VOID	DOCKET NUMBER	MAIL CONTROL NUMBER	CHANGE NAME/ADDRESS ("X" box)
NEW LICENSE AND NEW LICENSEE	XX	OTHER AMENDMENT		CLERICAL CHANGE NO AMENDMENT	4		030-14386	78085	

B. INDICATIVE INFORMATION

INDIVIDUAL LICENSEES	NAME (Last, First, Middle)	NAME (Last, First, Middle)
	NAME (Last, First, Middle)	NAME (Last, First, Middle)
	NAME (Last, First, Middle)	NAME (Last, First, Middle)
ORGANIZATION	ORGANIZATION NAME (Alphabetic Sequence) Nuclear Pharmacy, Inc.	
LICENSEES	DEPARTMENT OR BUREAU	
ADDRESS	BUILDING-STREET 319 W. Ontario	CITY Chicago — STATE IL — ZIP CODE 60610

TYPE OF APPLICANT			DATE REQUEST RECEIVED	INSTITUTION CODE	PENDING PROG. CODE	ACTUAL PROG. CODE
		U.S. GOVERNMENT AGENCY	1/10/85	18044		
	XX	INDIVIDUAL LICENSEE				
		ORGANIZATIONAL LICENSEE				

SECONDARY PROGRAM CODES (As required)

#1	#2	#3	#4	#5

LICENSE NUMBER	DATE LICENSE ISSUED OR ACTION COMPLETED	EXPIRATION DATE	
12-18044-01MD			
APPLICANT'S COMMUNICATION DATED	CLASSIFICATION	ASSIGNED TO	RESULTING AMENDMENT NUMBER

Combined with Control No 77191 after review 2/26/85 WJA

Ok LFMB

ENCLOSURES

recd 9/10/85
No refund due

UNCLASSIFIED DESCRIPTION

Lops completed 9/10/85 cap

DISTRIBUTION

78085 Jan 16 — Voided — Logged
77191 aug 4 (84) — Logged

OTHER REFERRALS

NAME	DATE	NAME	DATE

NRC Form 782 (1-82)

7—LICENSE FEE MANAGEMENT REFERENCE COPY