

New Berlin



Memorial Hospital

39-1346

RECEIVED

WILLIAM L. SCHWARTEN, Chief Executive Officer

'85 JUL 25 11:50

U.S. NRC
LIC. FEE MGMT. BRANCH

June 12, 1985

U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Re: NRC License No. 48-17608-01

Gentlemen:

This is a request to amend the above license to include the following changes:

Add: Russell Tobe, D.O. as an authorized user of by-product material. Dr. Tobe's training and experience and preceptor statements are enclosed.

Changes in Items 4, 7, 9, 11C and 13 (re: NRC 313M) as noted on the enclosed.

Enclosed is a check in the amount of \$120.00 to cover the amendment fee as listed for category 7.B.

Please inform us if any additional information should be required to complete this amendment.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Frank S. Sabor'.

FRANK S. SABOR
Chief Executive Officer

FSS/jd

encls.

8508090682 850719
REG3 LIC30
48-17608-01 PDR

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JUL 11 1985
REGION III

CONTROL NO. 7 9319

13750 WEST NATIONAL AVE. • 414-782-2700 • NEW BERLIN, WISCONSIN 53151

JUL 11 1985

30-13046

EXHIBIT A

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557			
INSTRUCTIONS – Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.					
1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE TELEPHONE NO.: AREA CODE () _____		1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE 			
2. PERSON TO CONTACT REGARDING THIS APPLICATION FRANK S. SABOR TELEPHONE NO.: AREA CODE (414) 782-2700		3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. 43-17608-01 c. <input type="checkbox"/> RENEWAL OF LICENSE NO. _____			
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)		5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)			
6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE					
RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III			GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA.		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
10 CFR 35.100, SCHEDULE A, GROUP VI					
6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)					
ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLCURIES OF EACH FORM	DESCRIBE PURPOSE OF USE		
<div style="border: 1px solid black; padding: 5px; width: fit-content;"> Applicant: <u>July 16, 1985</u> Check No. <u>25481</u> Amount/Fee Category <u>78</u> Type of Fee <u>ampl</u> Date Check Rec'd <u>7/16/85</u> Received By <u>[Signature]</u> </div>					

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Russell H. Tobe D.O.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE MICHIGAN, PENNA.
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3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Osteopathic Board of Radiology	Radiology	Board Eligible 8-1-84

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	Flint Osteopathic Hospital Michigan State University	60	150
b. RADIATION PROTECTION	Flint Osteopathic Hospital Michigan State University	60	150
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Flint Osteopathic Hospital Michigan State University	30	100
d. RADIATION BIOLOGY	Flint Osteopathic Hospital Michigan State University	35	15
e. RADIOPHARMACEUTICAL CHEMISTRY	Flint Osteopathic Hospital Michigan State University	20	10

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
T _{99m} C I125 I131 P32 Y169 Se 75 Xe 133	30 mCi 300 uCi 10 mCi 30 mCi 0.5 mCi 250uCi 11mCi	Flint Osteopathic Hospital	July 1981 to July 1984	diagnostic " therapy " diagnostic " "

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Russell H. Tobe, D.O.

STREET ADDRESS

Flint Osteopathic Hospital
3921 Beecher Rd.

CITY

Flint

STATE

Mich

ZIP CODE

48502

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	90	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	3	
	LIVER FUNCTION STUDIES	0	
	FAT ABSORPTION STUDIES	0	
	KIDNEY FUNCTION STUDIES	47	
	IN VITRO STUDIES	0	
OTHER	Gallium 67	24	
I-125	DETECTION OF THROMBOSIS	0	
I-131	THYROID IMAGING	90	
P-32	EYE TUMOR LOCALIZATION	0	
Se-75	PANCREAS IMAGING	12	
Yb-169	CISTERNOGRAPHY	3	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	69	
OTHER	Hepatobiliary Tc99m	80	
Tc-99m	BRAIN IMAGING	120	
	CARDIAC IMAGING	60	
	THYROID IMAGING	20	
	SALIVARY GLAND IMAGING	4	
	BLOOD POOL IMAGING	60	
	PLACENTA LOCALIZATION	0	
	LIVER AND SPLEEN IMAGING	250	
	LUNG IMAGING	80	
	BONE IMAGING	160	
OTHER	Renal Scan/ Testicular	45/10	

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	0	
P-32 (Colloid)	INTRACAVITARY TREATMENT	1	
I-131	TREATMENT OF THYROID CARCINOMA	0	
	TREATMENT OF HYPERTHYROIDISM	12	
Au-198	INTRACAVITARY TREATMENT	0	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	0	
Co-60 or Cs-137	TELETHERAPY TREATMENT	0	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION	0	
Mo-99/ Tc-99m	GENERATOR	35	
Sn-113/ In-113m	GENERATOR	0	
Tc-99m	REAGENT KITS	62	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

July 1981-July 1984 - 540 hours at Flint Osteopathic Hospital

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

A. NAME OF SUPERVISOR

Frank T. Stratton, D.O.

B. NAME OF INSTITUTION

Flint Osteopathic Hospital

C. MAILING ADDRESS

3921 Beecher Rd.

D. CITY

Flint, Michigan 48502

5. MATERIALS LICENSE NUMBER(S)

21-04074-01

6. PRECEPTOR'S SIGNATURE

Frank T. Stratton, Jr. D.O.

7. PRECEPTOR'S NAME (Please type or print)

Frank T. Stratton, Jr. D.O.

8. DATE

7/26/84

NEW BERLIN MEMORIAL HOSPITAL

ITEM 4. INDIVIDUAL USERS

Edward Aprahamian, D.O.	- Radiologist
Alex Romashko, D.O.	- Pathologist, Hematologist
Thomas Roskos, D.O.	- Radiologist
Richard E. Bush, D.O.	- Radiologist
Russel H. Tobe, D.O.	- Radiologist

ITEM 7. RADIATION SAFETY COMMITTEE

Edward Aprahamian, D.O., Radiologist, or designee

Alex Romashko, D.O., Pathologist, Hematologist, or designee

Carole Dellevar, R.N., Director of Nursing, or designee

Harry Torosian, R.T.R., Administration, or designee

ITEM 8. TRAINING AND EXPERIENCE

Previously Submitted Under NRC License No.:

Edward Aprahamian, D.O.	48-17608-01
Alex Romashko, D.O.	48-17608-01
Thomas Roskos, D.O.	48-15752-01
Richard E. Bush, D.O.	48-17608-01

APPENDIX C
INSTRUMENTATION

1. Survey meters

- a. Manufacturer's name: Ludlum
Manufacturer's model number: Model 3
Number of instruments available: 1
Minimum range: 0 mR/hr to .2 mR/hr
Maximum range: 0 mR/hr to 200 mR/hr
- b. Manufacturer's name: Victoreen
Manufacturer's model number: Model 740-F Cutie Pie
Number of instruments available: 1
Minimum range: 0 mR/hr to 25 mR/hr
Maximum range: 0 mR/hr to 25,000 mR/hr

2. Dose calibrator

Manufacturer's name: Picker
Manufacturer's model number: Model #632507Y
Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamm a Counter	Abbott Lab	ANSR Serial 333

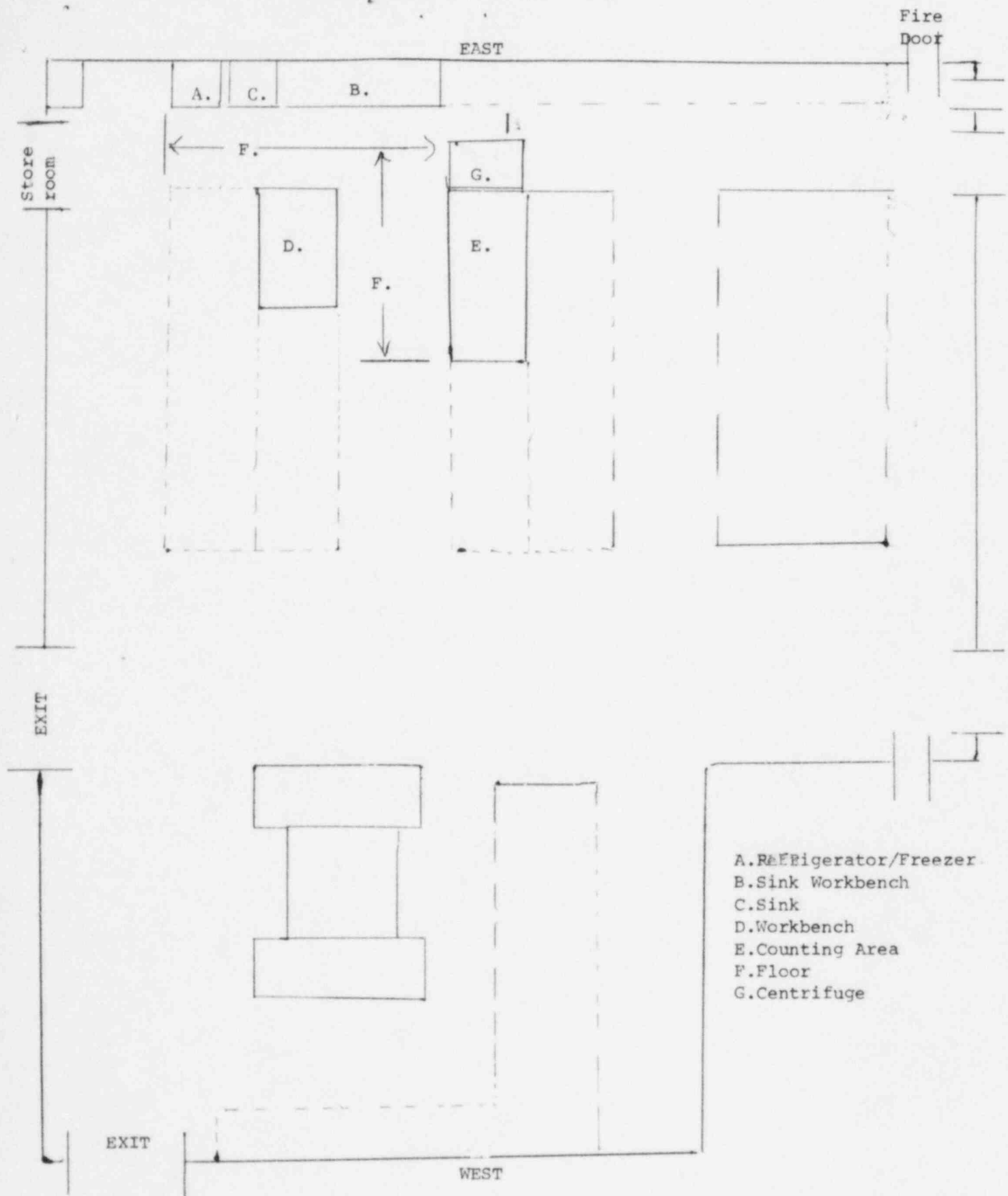
4. Other (e.g., liquid scintillation counter, area monitor, velometer) Picker Corp., Model #642-082 Labmonitor

Survey Meter

Picker Corp. Model 800
Minimum Range 0 mR/hr to .5 mR/hr
Maximum range 0 mR/hr to 50 mR/hr

313M Item 9
June, 1935

DIAGRAM OF RADIOASSAY LABORATORY



A. Refrigerator/Freezer
 B. Sink Workbench
 C. Sink
 D. Workbench
 E. Counting Area
 F. Floor
 G. Centrifuge

CONTROL NO. 7 9319

NEW BERLIN MEMORIAL HOSPITAL
ORDERING RADIOPHARMACEUTICALS

I. IMAGING DEPARTMENT

Unit doses are ordered by the Nuclear Medicine Technologist through Nuclear Pharmacy Inc., located in the Milwaukee area.

Each dose is recorded in a day log book with the name of the patient, amount of activity, volume dispensed, the radiopharmaceutical, the date, the time calibrated, lot number, the doctor, License #, Rx. #, hospital name, hospital code. At the time of administration, the time and amount of activity is recorded. The syringe is returned to the Nuclear Pharmacy Inc. and the date returned is recorded and initialed.

When ordering from a Radiopharmaceutical company other than the Nuclear Pharmacy Inc. a purchase order number is obtained from the Purchasing Director. He must know the name of the company with whom the order is being placed before a number is given out. The company is called directly by the technologist, after checking that the amounts ordered are correct and do not exceed the amounts authorized by the NRC license for the hospital. When the material is received, the packing slip and invoice are sent to the Purchasing Director.

II. RADIOASSAY LABORATORY

Kits may be obtained without a purchase order for evaluation, or with a purchase order for use. In either case, the NRC license number found on page 3 of the manual must be given if ordering individually, or the first time when establishing a standing order. Manufacturers and distributors must be notified if this number changes. Purchase order numbers are issued directly from the laboratory from the secretary/transcriber, the chemistry supervisor, or the lab manager. The limit on ordering for this laboratory is 5 millicuries of each byproduct material.

NEW BERLIN MEMORIAL HOSPITAL

RECEIPT OF RADIOACTIVE MATERIAL

The following procedures are followed for the receiving of packages of radioactive material at New Berlin Memorial Hospital.

I. NUCLEAR MEDICINE DEPARTMENT

NUCLEAR PHARMACY INC.: All packages coming from the Nuclear Pharmacy Inc. are brought unopened, directly to the Nuclear Medicine Dept. by the Nuclear Pharmacy carriers and placed in the designated area.

All packages coming from companies other than the Nuclear Pharmacy Inc. are delivered to the shipping/receiving area on the lower level of the hospital. They are then brought unopened, directly to the Nuclear Medicine Department and given to the Nuclear Medicine Technologist if on duty, or placed in the designated area.

II. RADIOASSAY LABORATORY

All packages arrive via common carrier or other private carrier and are delivered to the shipping/receiving area on the lower level of the hospital. From this point they are brought to the laboratory where they opened, inspected for damage, checked against the packing slip, and dated using the labeling gun. The packing slip is time stamped and initialed, and placed in the packing slip receiving box on top of the file cabinet in the secretarial area.

CONTROL NO. 7 9319