NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041

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	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE
Frankford-Mayfair Diagnostic Services 6200 Medical Building-Suite B 6200 Frankford Ave. Philadelphia, PA 19135 TELEPHONE NO.: AREA CODE (215) 535-1214	Same 29-L725P
2. PERSON TO CONTACT REGARDING THIS APPLICATION Walter L. Robinson, M.S. Lancaster, PA 17601 TELEPHONE NO.: AREA CODE (717) 397-2569	3. THIS IS AN APPLICATION FOR: *(Check appropriate item)* a. ☐ NEW LICENSE b. ☐ AMENDMENT TO LICENSE NO. _____ c. ☒ RENEWAL OF LICENSE NO. 37-19272-01
4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)* Daniel Pisano, M.D. R. Stokes, M.D. David Sabbar, M.D. Denis G. Zervos, M.D.	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.)* Daniel Pisano, M.D., residing Walter L. Robinson, M.S. and Jack O'Sullivan, consulting

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2,000
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

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 MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
			License Fee Information on Next Page 5/15/85 eeg

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 Rev. 1 Date: October, 1980

Appendix O Alara Program confirmed

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and See cover letter
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or with cover letter *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or with cover letter *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
	Description of Training Attached (See cover letter) (same)
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached as per appendix E
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer & Sons	monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R. S. Landauer & Sons	monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL: Frankford Hospital (Frankford Division)

MAILING ADDRESS: Frankford & Wakeling Sts.

CITY: Philadelphia, STATE: Pa. ZIP CODE: 19124

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: 7 c.

(2) LICENSE FEE ENCLOSED: $ $580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*: Daniel J. Pisano

(1) NAME *(Type or Print)*: Daniel Pisano, M.D.

(2) TITLE: Director of Radiology & Nuclear Medicine

c. DATE:

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Picker G.M.

   Manufacturer's model number: 655-186

   Number of instruments available: 1

   Minimum range: 0.01 mR/hr to 0.2 mR/hr

   Maximum range: 10.0 mR/hr to 2000 mR/hr

   b. Manufacturer's name: G.M. Monitor by Picker

   Manufacturer's model number:

   Number of instruments available: 1

   Minimum range: _____ mR/hr to _____ mR/hr c/m only

   Maximum range: _____ mR/hr to _____ mR/hr

2. Dose calibrator

   Manufacturer's name: Picker Digital

   Manufacturer's model number: N/A

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Picker	4/11/37
Thyroid Uptake Probe	Picker	N/A

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

none

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

X 1. Survey instruments will be calibrated at least annually and following repair.

X 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

____ a. By the manufacturer

____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

X (2) The calibration procedures in Section I of Appendix D will be used
or

____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

X c. By a consultant or outside firm

(1) Name Radiation Management Corp. or Nuclear Pharmacy, Inc., Philadelphia, PA

(2) Location Market St., Philadelphia, PA

(3) Procedures and sources

RMC NRC # 37-13129-01

X have been approved by NRC and are on file in License No. NPI NRC# - See Below

____ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

____ the attached "Certificate of Instrument Calibration."
____ the consultant's reporting form as attached.

____ are described in the attachment, and the consultant's report will contain the information on

____ the attached "Certificate of Instrument Calibration."
____ the consultant's reporting form as attached.

Nuclear Pharmacy, Inc.
Van Nuys, Calif. #3822-70
Houston, Texas #11-1911
Approved by amendment to
Philadelphia NRC #37-18461MD

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

_____ First elution from new Mo-99/Tc-99m generator

or

__X__ Other* (specify) See S.C.L.C.M. Procedure attached

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	1.0-3.0	+/- 4%
Ba-133	0.1-0.5	0.2	+/- 4%
Cs-137	0.1-0.2		
Ra-226	1-2		

C. _X_ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator except as stated in the cover letter.

or

_____ Equivalent procedures are attached.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

Please amend our NRC License # _____ to include the following procedure for dose calibrator activity linearity check in lieu of our current procedure (that implied in NRC Reg. Guide 10.8 Appendix D., Part E, p. 10.8 - 27 to 28).

The new procedure is as follows:

The procedure is similar to the commercially available "Calcorp" sequential lead cylinder method. The variance in our method is that it is a Sequential Concentric Lead Cylinder Method (SCLCM). A lead disk is placed in the bottom of the radioisotope calibrator "dipper". Then sequentially 5 lead cylinders are concentrically placed over top of each other for 5 successive reductions in "apparent" assay readings. Then a lead disk is placed on top of the cylinders column , and a 6th reading is made. These values are reported on the enclosed form.

The lead effects a contrived degradiation of radiation intensity measured over the useful range of assay values from total eluate activity to micro curie quantities. The effective "decay-equivalent" hours evolved empirically and averaged over 20 trials are as follows:

shield 1 = 18.93 hrs. ± 3.9%
shield 2 = 27.88 hrs. ± 2.4%
shield 3 = 35.87 hrs. ± 3.1%
shield 4 = 43.05 hrs. ± 1.3%
shield 5 = 47.88 hrs. ± 2.8%
Top lid = 53.90 hrs. ± 2.6%

The assayed values are divided by the original unshielded total eluate assay for a fraction (decimal).

The natural log of this decimal is divided by 0.1155*0.693/6hr.) to equal the "calculated effective time elapsed". This calculated value is compared with the empirically-determined values of "shielded - effective hours". A percent variance is calculated. The mean of the 6 variances is tabulated and compared for quarterly changes. Notation is made if the unit is autoranging or not. A plot is then made of assayed shielded values versus calculated elapsed time to assure acceptable linearity and ± 5% precision.

The summation of error between run variability, between instrument variability, geometric mispositioning, and high to low original activity all add to ≤ ± 3.9% for each measurement. Since this is within ± 5%, and consistent with our previous method, we submit this as our alternative method to comply with the intent of the NRC rules governing this check.

We are able to do the check quarterly or more frequently now with total eluate without loss of the use of that eluate clinically. We can do the check in less than 5 minutes, thus saving technological and professional time which is cost -effective and within A.L.A.R.A. constraints in our institution.

The method was refined by our consultant radiation physicist, Walter L. Robinson, M.S. A.B.S.N.M. (phone-(717) 397-2569), who can be contacted for further details on the method.

It is hoped that this information will be adequate for you to assess the equivalency of our proposed procedure to our existing one

DOSE CALIBRATOR ACTIVITY LINEARITY CHECK — Tc-99m

	Assay	Calc. Hrs.	Shield Effect Hrs.	% Variance
Shield #0			0	
Shield # 1			18.93	
Shield # 2			27.88	
Shield # 3			35.87	
Shield # 4			43.05	
Shield # 5			47.88	
Top Lid			53.90	

Mean Variance: $\bar{X}$ = ____

This ____ ≤ ± 5% Therefore ____

Measurement Error : ± 3.9%

Mean Variance is ____% of last Quarter's check. Therefore:

____

____

____

This unit is Autoranging

Yes ___ No ___

MILLICURIES OR % OF ORIGINAL ACTIVITY

100 90 80 70 60 50 40 30 20 10 9 8 7 6 5 4 3 2 1.0 0.9 0.8 0.7 0.6 0.5 0.4 0.3 0.2 0.1 0

0 3 6 9 12 15 18 21 24 30 36 42 48 54 60 66 72 84

Walter L. Robinson & Associates
Consultant Radiation Physicists
Diagnostic Imaging Specialists
2624 Spring Valley Rd.
Lancaster, PA 17601

Measured By: ____

Date : ____

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

_____ In the sanitary sewer system in accordance with § 20.303 of 10 CFR Part 20.

_____ By commercial waste disposal service (see also Item 4 below).

_X_ Other (specify): decayed to background and returned to the radiopharmacy

2. Mo-99/Tc-99m generators will be (check as appropriate)

_X_ Returned to the manufacturer for disposal.

_____ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate)

_X_ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_X_ Other (specify): decayed to background and returned to the radiopharmacy

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

*Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

**These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

Address change

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED

Applicant/Licensee: Frankford Mayfair Diagnostic Services

Application Dated: 2/1/85

Control No.: 03426

License No.: 37-19272-01

2. FEE ATTACHED

Amount: $580.00

Check No.: 2584

3. COMMENTS

7C
3/31/85

Signed _____

Date _____

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C #580

2. Correct Fee Paid. Application may be processed for:

Amendment _____

Renewal ✓

License _____

Signed Frances Braun

Date 2/19/85 ✓ 2/20/85

REGION I FORM 213
(MARCH 1983)