30-17250

NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041 Expires 9-30-83

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

Physicians Associates
6200 Medical Building-Suite B
Philadelphia, PA 19135

TELEPHONE NO. AREA CODE (215) 535 1960

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

1. same as 1a.

2. 6545 Roosevelt Blvd.
Philadelphia, PA 19149

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Daniel Patrick

TELEPHONE NO. AREA CODE (215) 532 2248

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 37-19272-01
c. ☐ 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.)*

same

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.

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		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
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

The purpose of this amendment is to include an additional location where radioactive material will be used.

License Fee Information on page 3.

16 SEP 1987

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REG1 LIC30
37-19272-01 PDR

NRC FORM 313M (9-81)

"OFFICIAL RECORD COPY" ML18

107822

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. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and
	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)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or _____ *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or _____ *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
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)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADICPHARMACEUTICALS *(Check One)*	
	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)	
	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		FILM		
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

107822

Log 04.3 F
Remitter
Check No. 1253
Amount $120
Fee Categ 7C
Type of Fee AMD
Date Check Rec'd. 10/2/87
Date Completed 10/5/87
By: D. Hamby

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

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: 7C

(2) LICENSE FEE ENCLOSED: $ 120.00

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)

X [signature]

(1) NAME (Type or Print)

X DANIEL J. DISANO M.D.

(2) TITLE

X R.S.O.

c. DATE

X 9-11-87

NRC FORM 313M (9-81)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC 3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

APPENDIX C

INSTRUMENTATION

1. Survey meters

**a. Manufacturer's name: Victoreen

Manufacturer's model number: 290 Thyac IV

Number of instruments available: 1

Minimum range: 0 mR/hr to .1 mR/hr

Maximum range: 0 mR/hr to 1000 mR/hr

b. Manufacturer's name: Atomic Products

Manufacturer's model number: 051-744

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(s)

Manufacturer's name: Atomic Products

Manufacturer's model number: 086-307

Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera/Computer	Baird	System 77
Gamma Camera	Technicare	Sigma 414
Computer	Technicare	M.C.S. 560

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

**coupled with Victoreen Probe Model 425-110 for analyzing wipe smears.

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Atomic Products

      Manufacturer's model number: 069-310

      Number of instruments available: 1

      Minimum range: 0 mR/hr to .15 mR/hr

      Maximum range: 0 mR/hr to 15 mR/hr

   b. Manufacturer's name:

      Manufacturer's model number:

      Number of instruments available:

      Minimum range: mR/hr to mR/hr

      Maximum range: mR/hr to mR/hr

2. Dose Calibrator(s)

   Manufacturer's name:

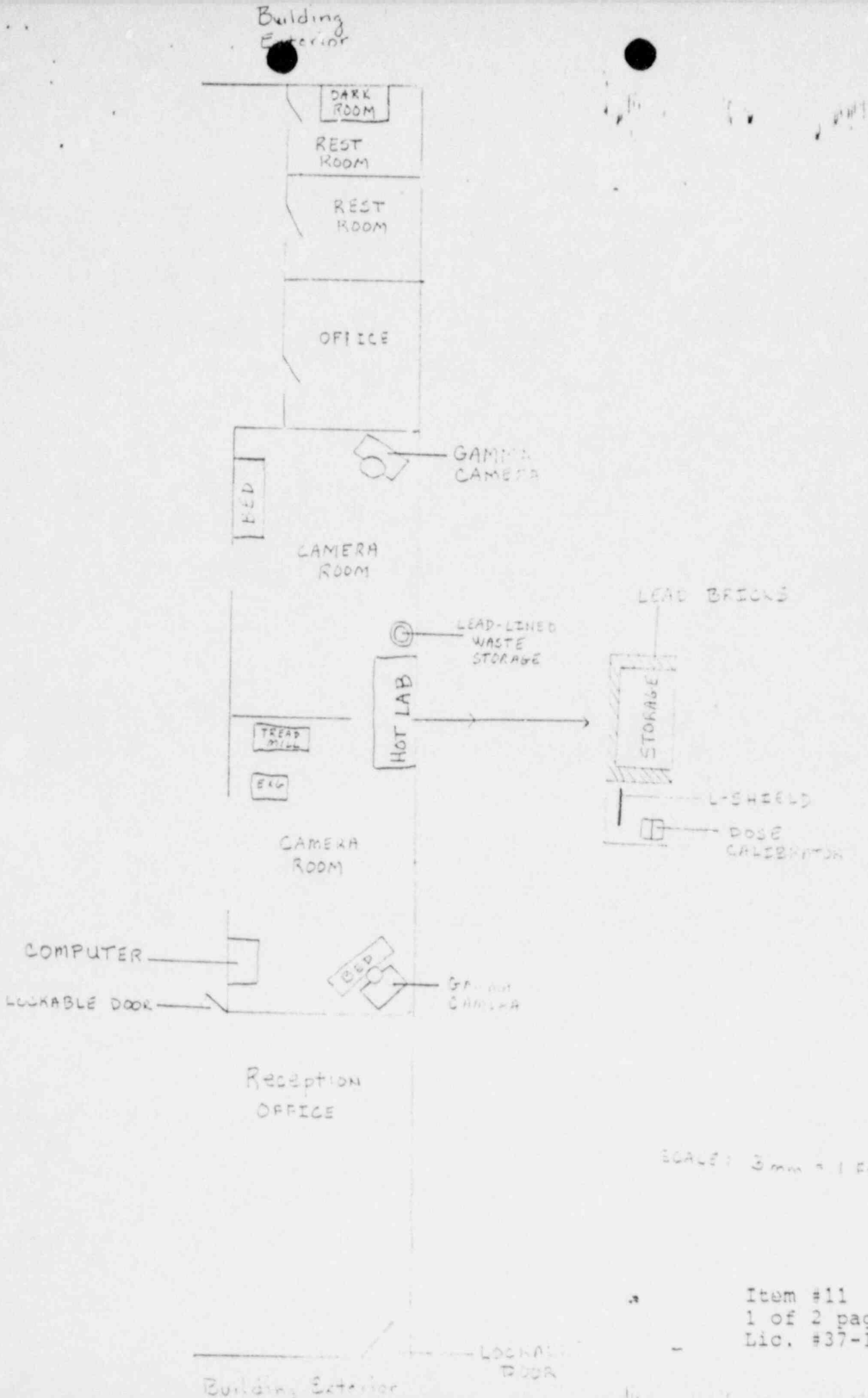
   Manufacturer's model number:

   Number of instruments available:

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.

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



ADJOINING BUSINESS

ADJOINING BUSINESS

SCALE: 3mm = 1 Ft

Item #11
1 of 2 pages
Lic. #37-19272-01

FACILITIES AND EQUIPMENT DESCRIPTION

All radioactive sources are stored in such a manner (lead, concrete) so as to not exceed 2mR/hr at the surface of the barrier.

Radioactive materials will be obtained from a radiopharmacy supplier. A generator will not be used. Radioactive materials obtained from radiopharmacy suppliers will be stored in their original shipping containers. If necessary, the doses will be placed behind additional shielding to reduce activity levels emitted from the container to 2mR/hr or less.

Syringe shields will be used on all accessories requiring the transfer of radiopharmaceuticals from vial to vial. Syringe shields will also be used in the administration of doses to patients except when the patient's well-being may be compromised. Under these circumstances, the dose containing syringes will be kept shielded up to the moment of injection.

Protective outer garments, such as laboratory coats and rubber gloves will be worn while handling radioactivity in uncontained form.

In regard to equipment, the Victoreen Survey Meter will be used in conjunction with the Victoreen Model Probe 425-110 in order to analyze wipe smears.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The chief nuclear medicine technologist or his/her designee will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license, and that possession limits are not exceeded. The receipt area identified in the Item #11 diagram is designed such that radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the isotope receipt area. If this is not practical, responsible personnel (indicated in the memorandum below) will sign for packages containing radioactive materials and immediately take them to this location. Alternatively, trained nuclear medicine personnel will sign for and transport packages to the appropriate department.

3. During off-duty hours, supervisory personnel will arrange to have delivery of radioactive packages in accordance with the procedures outlined in the following directive:

TO: Physicians Associates Personnel

FROM: Dr. Pisano

SUBJECT: Delivery of packages containing radioactive materials

If couriers or common carriers attempt delivery of packages containing radioactive materials, the supervisor on duty will be contacted. He/she will have the carrier escorted to the receipt area by personnel who have been assigned this duty. Alternatively, clinic personnel will deliver the package to the receipt area. Under these conditions, people transporting the packages will receive special training for this purpose. Personnel not trained in the proper handling of radioactive materials are not to personally accept packages containing radioactive materials. The packages will be secured against unauthorized removal. When delivered packages are wet or appear to be damaged, the RSO is to be immediately contacted.* The carrier should be requested to remain until it can be determined that neither he nor the delivery vehicle is contaminated. Alternatively, the courier will be given keyed access to the receipt area to secure the delivery.

*Radiation Safety Officer: Dr. Pisano
576-0743 (H)
535-1212 (O)

APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of:

A. In the sanitary sewer system in accordance with 20.303 of 10 CFR, Part 20.

B. 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 as normal trash.

C. Other (specify): Return to Radiopharmacy (if applicable).

Item #18
Prepared 8/25/87
Lic #37-19272-01

30-17250
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6/90

BETWEEN: C. James Holloway, Chief
License Fee Management Branch
Office of Resource Management

John E. Glenn, Chief
Nuclear Materials Safety & Safeguards Section B
Division of Radiation Safety and Safeguards

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED

Applicant/Licensee: Physicians Associates

Application Dated: September 11, 1987

Control No.: 107822

License No.: 37-19272-01

2. FEE ATTACHED

Amount: 120

Check No.: 1253

3. COMMENTS

Signed bp

Date 9/29/87

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C $120

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

Amendment ✓

Renewal

License

Signed S. Kimberly

Date 10/5/87

REGION I FORM 213
(MARCH 1987)