

EXHIBIT A

Log *Oct 18 1987*
 Remitted *Southwest Medical*
 Check No. *637*
 Amount *\$120*
 Fee Category *76*
 Type of Fee *and*
 Date Check Rec'd. *10/26/87*
 Date Completed *10/26/87*
 By: *85*

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE — MEDICAL		Approved: GAO R0557																																																
<p>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.</p>																																																			
<p>1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE</p> <p>South West Medical Center 3915 Watson Rd. St. Louis MO 63109</p> <p>TELEPHONE NO.: AREA CODE (314) 644-7100</p>		<p>1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE</p> <p>Same as 1a</p>																																																	
<p>2. PERSON TO CONTACT REGARDING THIS APPLICATION</p> <p>Mark Beanblossom, Consultant N.M.A. Medical Physics Service</p> <p>TELEPHONE NO.: AREA CODE (314) 427-5833</p>		<p>3. THIS IS AN APPLICATION FOR: (Check appropriate item)</p> <p>a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. _____ c. <input type="checkbox"/> RENEWAL OF LICENSE NO. _____</p>																																																	
<p>4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)</p>		<p>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.)</p>																																																	
<p>6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE</p> <table border="1"> <thead> <tr> <th>RADIOACTIVE MATERIAL LISTED IN:</th> <th>ITEMS DESIRED "X"</th> <th>MAXIMUM POSSESSION LIMITS (in millicuries)</th> <th>ADDITIONAL ITEMS:</th> <th>MARK ITEMS DESIRED "X"</th> <th>MAXIMUM POSSESSION LIMITS (in millicuries)</th> </tr> </thead> <tbody> <tr> <td>10 CFR 31.11 FOR IN VITRO STUDIES</td> <td></td> <td></td> <td>IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM</td> <td></td> <td></td> </tr> <tr> <td>10 CFR 35.100, SCHEDULE A, GROUP I</td> <td></td> <td>AS NEEDED</td> <td>PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES</td> <td></td> <td></td> </tr> <tr> <td>10 CFR 35.100, SCHEDULE A, GROUP II</td> <td></td> <td>AS NEEDED</td> <td>PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS</td> <td></td> <td></td> </tr> <tr> <td>10 CFR 35.100, SCHEDULE A, GROUP III</td> <td></td> <td></td> <td>GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS</td> <td></td> <td></td> </tr> <tr> <td>10 CFR 35.100, SCHEDULE A, GROUP IV</td> <td></td> <td>AS NEEDED</td> <td>IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA</td> <td></td> <td></td> </tr> <tr> <td>10 CFR 35.100, SCHEDULE A, GROUP V</td> <td></td> <td>AS NEEDED</td> <td>XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES</td> <td></td> <td></td> </tr> <tr> <td>10 CFR 35.100, SCHEDULE A, GROUP VI</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>				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					
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																																																			
<p>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.)</p> <table border="1"> <thead> <tr> <th>ELEMENT AND MASS NUMBER</th> <th>CHEMICAL AND/OR PHYSICAL FORM</th> <th>MAXIMUM NUMBER OF MILLICURIES OF EACH FORM</th> <th>DESCRIBE PURPOSE OF USE</th> </tr> </thead> <tbody> <tr> <td>Item 11 change in facility description 21 change in procedure for use of Radioactive Xe-133 gas</td> <td></td> <td></td> <td></td> </tr> <tr> <td>8805090087 871023 REG3 LIC30 24-09769-01 PDR</td> <td></td> <td></td> <td></td> </tr> <tr> <td colspan="2">CONTROL NO. 84321</td> <td></td> <td></td> </tr> </tbody> </table>				ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE	Item 11 change in facility description 21 change in procedure for use of Radioactive Xe-133 gas				8805090087 871023 REG3 LIC30 24-09769-01 PDR				CONTROL NO. 84321																																			
ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE																																																
Item 11 change in facility description 21 change in procedure for use of Radioactive Xe-133 gas																																																			
8805090087 871023 REG3 LIC30 24-09769-01 PDR																																																			
CONTROL NO. 84321																																																			

OCT 19 1987
REGION III

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		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
<input type="checkbox"/>	Names and Specialties Attached; and	<input type="checkbox"/>	Appendix G Rules Followed; or
<input type="checkbox"/>	Duties as in Appendix B; or _____ (Check One)	<input type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		<input type="checkbox"/>	Appendix H Procedures Followed; or
<input type="checkbox"/>	Supplements A & B Attached for Each Individual User; and	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		<input type="checkbox"/>	Appendix I Procedures Followed; or
<input type="checkbox"/>	Appendix C Form Attached; or	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	List by Name and Model Number	18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS		<input type="checkbox"/>	Appendix J Form Attached; or
<input type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)	<input type="checkbox"/>	Equivalent Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)	<input type="checkbox"/>	Appendix K Procedures Followed; or
<input type="checkbox"/>	Equivalent Procedures Attached	<input type="checkbox"/>	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
<input checked="" type="checkbox"/>	Description and Diagram Attached	<input type="checkbox"/>	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM		<input type="checkbox"/>	Appendix L Procedures Followed; or _____ (Check One)
<input type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
<input type="checkbox"/>	Detailed Information Attached	<input checked="" type="checkbox"/>	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
<input type="checkbox"/>	Appendix F Procedures Followed; or	<input type="checkbox"/>	Detailed Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
<input type="checkbox"/>		<input type="checkbox"/>	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)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL			b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.
NAME OF HOSPITAL			
MAILING ADDRESS			
CITY	STATE	ZIP CODE	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)	b. APPLICANT OR CERTIFYING OFFICIAL (Signature)
	(1) NAME (Type or Print)
(1) LICENSE FEE CATEGORY: 7C	(2) TITLE
(2) LICENSE FEE ENCLOSED: \$ 120.00	c. DATE

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 Form NRC-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.

Facilities and Equipment

Diagram

- ☒ Air Supply
- ☒ Air Exhaust

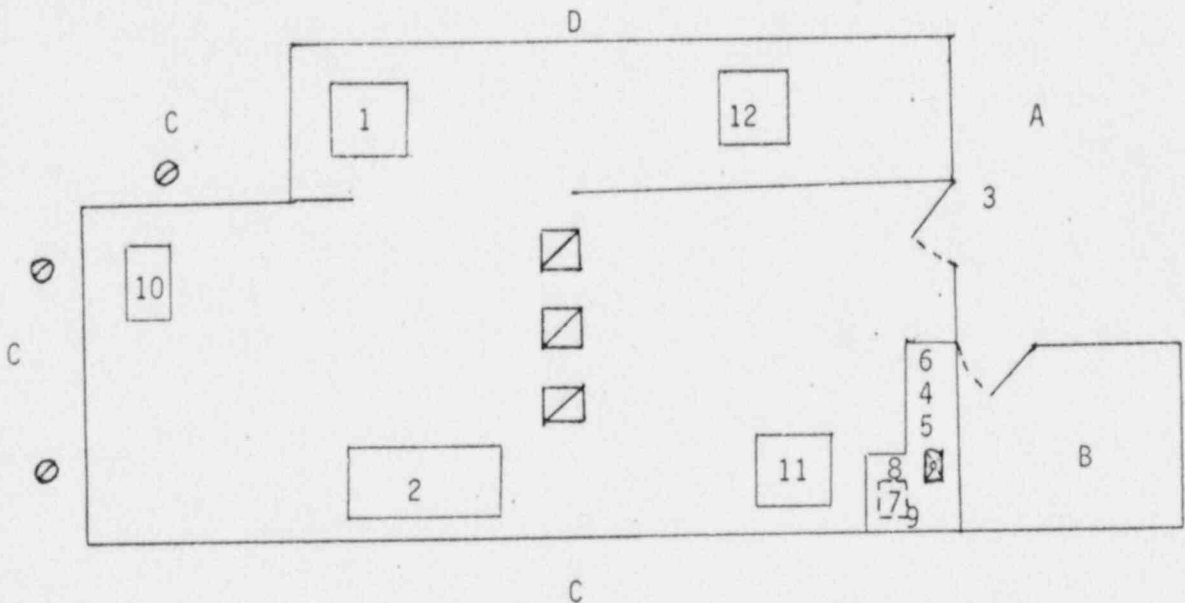
- Scanner
- 1 Uptake/Well
- 2 Camera
- 3 Lockable Door
- 4 Receipt Area
- 5 Generator
- 6 Kit Preparation
- 7 Isotope Storage
- 8 Dose Preparation
- 9 Waste Storage
- 10 Dose Calibrator
- 11 Refrigerator
- 12 Xenon Unit

Adjacent Areas

- A Hall
- B Restroom
- C Exterior
- D Storage
-
-
-
-

- ☒ Sink
- ☐ Lead Castle
- Lead Shielding

- ___ L x ___ W x ___ H x ___ T
- ___ L x ___ W x ___ H x ___ T
- ___ L x ___ W x ___ H x ___ T
- ___ L x ___ W x ___ H x ___ T



Item #11
 1 of 1 pages
 Prepared
 Lic. #24-09769-01

CONTROL NO 84321

ITEM #21

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

1) Quantities to be used:

a) Patient Information

- 1) One study per month
- 2) 6 mCi per study

b) Possession Limit: 100 mCi

2) Use and storage areas

The imaging room is used for the storage and use of Xenon.
(See diagram).

3) Procedures for Routine Use

- a) The dose will be prepared and assayed in the dose calibrator. If possible, shielding of the dose will be maintained at all times up to patient administration, except during identification and assay. Patients will be instructed as to the procedure and trial runs will be conducted if at all possible. Finger badges and whole body badges will be worn by all personnel handling Xenon. The camera room door will be closed.
- b) Face masks or mouthpieces along with a Xenon rebreathing charcoal trap apparatus will be employed (Radx Ventilcon-1). The face mask covers both mouth and nose. A nose clamp will be employed with the use of a mouthpiece. Tubing and valves will be inspected prior to use to assure continuity.
- c) Air flow measurements will be taken semi-annually to verify exhaust rates as stated, and to assure negative pressure in the camera room with respect to the hallway.

4) Concentration in Restricted Areas

- a) The air handling system of the camera room exhausts at a rate of 2000 cfm. No air is recirculated in the building. Supplies to the room will be dampered (if necessary) to achieve negative pressure in the room.
- b) Activity (A) = 6,000 uCi per month.
Loss Factor (f) = 20% (patient associated losses).
- c) Room Volume = 36' x 24' x 8' = 3936 cu. ft.

$$3936 \text{ cu. ft.} \times 2.832 \times 10^4 \text{ ml/cu. ft.} \times 2000 \text{ cfm} \times 16 \text{ hrs} \times 60 \text{ min/hr} = 2.8 \times 10^{14} \text{ ml.}$$

$$\text{Concentration (C)} = (A \times f)/V$$

$$C = \frac{6,000 \text{ uCi/month} \times .20}{2.8 \times 10^{14}} = 1.3 \times 10^{-11}$$

5) Emergency Procedures

- a) In the event a dose of Xenon is accidentally released into the camera room, the room will be evacuated until levels have reduced to 1×10^{-5} uCi/ml. Removal of personnel will be effected if the patient's condition permits. The time required for this evacuation is described below:

Assume 100% loss to the room.

Activity = 6 mCi = 6,000 uCi

Room Volume = 3936 cu. ft. = 1.1×10^8 ml

Initial Concentration (C_0) = $6,000 \text{ uCi} / 1.1 \times 10^8 = 5.5 \times 10^{-5} \text{ uCi/ml}$

Clearance Rate (CR) = $2,600 \text{ cfm} / 3936 \text{ cu. ft.} = 3.12 \text{ minutes}$

Concentration = $C_0 e^{-CR \times t}$

$1 \times 10^{-5} = 5.5 \times 10^{-5} e^{-RT}$

$= \log. 5.5 \times 10^{-5} \times .66T \log e$

$t = \log 1 \times 10^{-5} - \log 5.5 \times 10^{-5}$

$.66 \log e$

$t = 3 \text{ minutes}$

Prior to re-entry, a measurement will be made using a low level G-M survey meter near the floor. A reading equivalent to background shall be considered as evidence that the ventilation has cleared the room of Xenon as calculated.

6) Concentrations in Unrestricted Areas

On-time = 4.5 hrs

6,000 uCi/study

$2600 \text{ cfm} \times 3 \times 10^{-7} \text{ uCi/ml} \times 2.83 \times 10^4 \text{ ml/cu. ft.} \times 60 \text{ min/hr}$

Therefore, for each study, the fan will remain on for 4.5 hours.

7. Disposal of Xenon

After each study, the Xenon collected in the bag will be expelled out the exhaust fan. The bag will be collapsed into the exhaust fan by the technologist. When the bag is surveyed and found to be background, the bag may be disposed of to routine trash.

Item #21

Page 2 of 3

Lic. #24-09769-01

- 8) After every 20 procedures, the trapping efficiency of the charcoal trap will be evaluated. A low-level G-M probe will be placed against the inlet tube of the trap during the equilibrium phase of the study and a reading taken. The probe will then be placed against the outlet from the trap at the initiation of the washout phase. The maximum reading during washout will be noted. If the maximum exhaust reading exceeds 10% of the inlet reading, taking background into consideration, the trap will be considered to be saturated and the cartridge will be replaced.

Saturated filters will be stored for decay in the hot lab with sufficient shielding so that levels do not exceed 2.0 mR/hr at the shielded surface. Material will be held for $10t_{1/2}$'s, surveyed to determine levels of exposure at background and discarded.

Item #21
Page 3 of 3
Lic. #24-09769-01

CONTROL NO. 84321