| NRC FORM 313M (9-81) 10 CFR 35 | U.S. NUCLEAR REGULATORY COMMISSION<br>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

Elyria Memorial Hospital
630 East River Street
Elyria, Ohio 44035

TELEPHONE NO. AREA CODE( 216 323-3221

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

David Close, Consultant, Nuclear Medicine Associates

TELEPHONE NO. AREA CODE( 216) 641-5799

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 34-04307-02
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.)*

See Item #8.

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.)*

Amend to change RSO from:
Paul F. Varley, M.D. to
Mario Macchi, 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 | X | 300 |

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 |
|---|---|---|---|
| | | | |

8509120098 850827
REG3 LIC30
34-04307-02 PDR

Applicant Aug 24 '11
Check No. 16514 $150
Amount/Fee Category 7C amd
Type of Fee
Date Check Rec'd 8/28/85
Received By

CONTROL NO. 79591

## 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)* |
| ☐ Names and Specialties Attached; and | ☐ Appendix G Rules Followed; or |
| ☐ Duties as in Appendix B; or _____ *(Check One)* | ☐ Equivalent Rules Attached |
| ☐ Equivalent Duties Attached | 16. EMERGENCY PROCEDURES *(Check One)* |
| 8. TRAINING AND EXPERIENCE | ☐ Appendix H Procedures Followed; or |
| ☐ Supplements A & B Attached for Each Individual User; and | ☐ Equivalent Procedures Attached |
| ☐ Supplement A Attached for RSO. | 17. AREA SURVEY PROCEDURES *(Check One)* |
| 9. INSTRUMENTATION *(Check One)* | ☐ Appendix I Procedures Followed; or |
| ☐ Appendix C Form Attached; or | ☐ Equivalent Procedures Attached |
| ☐ List by Name and Model Number | 18. WASTE DISPOSAL *(Check One)* |
| 10. CALIBRATION OF INSTRUMENTS | ☐ Appendix J Form Attached; or |
| ☐ Appendix D Procedures Followed for Survey Instruments; or _____ *(Check One)* | ☐ Equivalent Information Attached |
| ☐ Equivalent Procedures Attached; and | 19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)* |
| ☐ Appendix D Procedures Followed for Dose Calibrator; or _____ *(Check One)* | ☐ Appendix K Procedures Followed; or |
| ☐ Equivalent Procedures Attached | ☐ Equivalent Procedures Attached |
| 11. FACILITIES AND EQUIPMENT | 20. THERAPEUTIC USE OF SEALED SOURCES |
| ☐ Description and Diagram Attached | ☐ Detailed Information Attached; and |
| 12. PERSONNEL TRAINING PROGRAM | ☐ Appendix L Procedures Followed; or _____ *(Check One)* |
| ☐ Description of Training Attached | ☐ Equivalent Procedures Attached |
| 13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL | 21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133) |
| ☐ Detailed Information Attached | X 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 |
| | ☐ Detailed Information Attached |
| ☐ Appendix F Procedures Followed; or | 23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b |
| ☐ Equivalent Procedures Attached | ☐ Detailed Information Attached |

## 24. PERSONNEL MONITORING DEVICES

| TYPE (Check appropriate box) | | | SUPPLIER | EXCHANGE FREQUENCY |
|---|---|---|---|---|
| a. WHOLE BODY | X | FILM | R.S. Landauer, Jr. & Sons | Monthly |
| | | TLD | | |
| | | OTHER (Specify) | | |
| b. FINGER | | FILM | | |
| | X | TLD | R.S. Landauer, Jr. & 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

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 Donald R. Taylor

(2) TITLE

X Administrator

c. DATE

X August 5, 1985

RECEIVED
AUG 19 1985
REGION III

NRC FORM 313M (9-81)



CONTROL NO. 79591

## 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.

The purpose of this amendment application is:

1. To notify the NRC of a change in our film badge vendor to R.S. Landauer, Jr. and Sons. See Item #24.

2. To update our authorized users list. See Item #8.

3. To notify the NRC of the upcoming move of the nuclear medicine department within the hospital. The new department is currently under construction and it will be several months until the move is actually made. See the enclosed Item #11 for the floorplan of the new department and Item #21 for the Xenon program for the new department.

   Upon vacating the current department, a close-out survey will be performed prior to releasing the area for unrestricted use. The close-out survey will consist of a series of wipe tests and radiation level measurements. The area will not be released unless radiation levels are less than 0.2 mR/hr at one cm and removable contamination does not exceed 200 dpm/100 $cm^2$. All sealed sources will be removed from the area. The results of the close-out survey will be retained on file for review. The results will include a diagram of the facility with the survey and wipe test results keyed to their locations, the date of the survey, the name of the individual performing the survey and the instruments used for the survey measurements and wipe test analysis.

4. Change of RSO.

| NAME OF AUTHORIZED USER | AUTHORIZATION |
|---|---|
| **Add as Authorized Users** | |
| Fredrick H. Dengel, M.D. | Groups I, II, III, Xenon-133 |
| Leon Nazarian, M.D. | Groups I, II, III, Xenon-133 and I-131 for treatment of hyperthyroidism |
| William Ferber, M.D. | Groups I, II, III, Xenon-133 and I-131 for treatment of hyperthyroidism |
| **Add the Following Uses for These Physicians** | |
| Karoly Szentendrey, M.D. | Groups II, III and Xe-133 |
| Stephen M. Ticich, M.D. | Group V |
| Teresita S. Ocampo, M.D. | I-131 for treatment of hyperthyroidism |
| Richard K. Lenhart, M.D. | I-131 for treatment of hyperthyroidism |

For training and experience of all the above, see license #34-17796-01, Lorain Community Hospital.

Delete

John F. Cardella, M.D.

**Item #8**
1 **of** 1 **page**
**Prepared:** 7/2/85
**Lic. #**34-04307-02

CONTROL NO. 7 9591

1084

## 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
5 Isotope Storage
6 Dose Preparation
5 Waste Storage
7 Dose Calibrator
4 Refrigerator

8 Fume Hood

Sink

Lead Castle

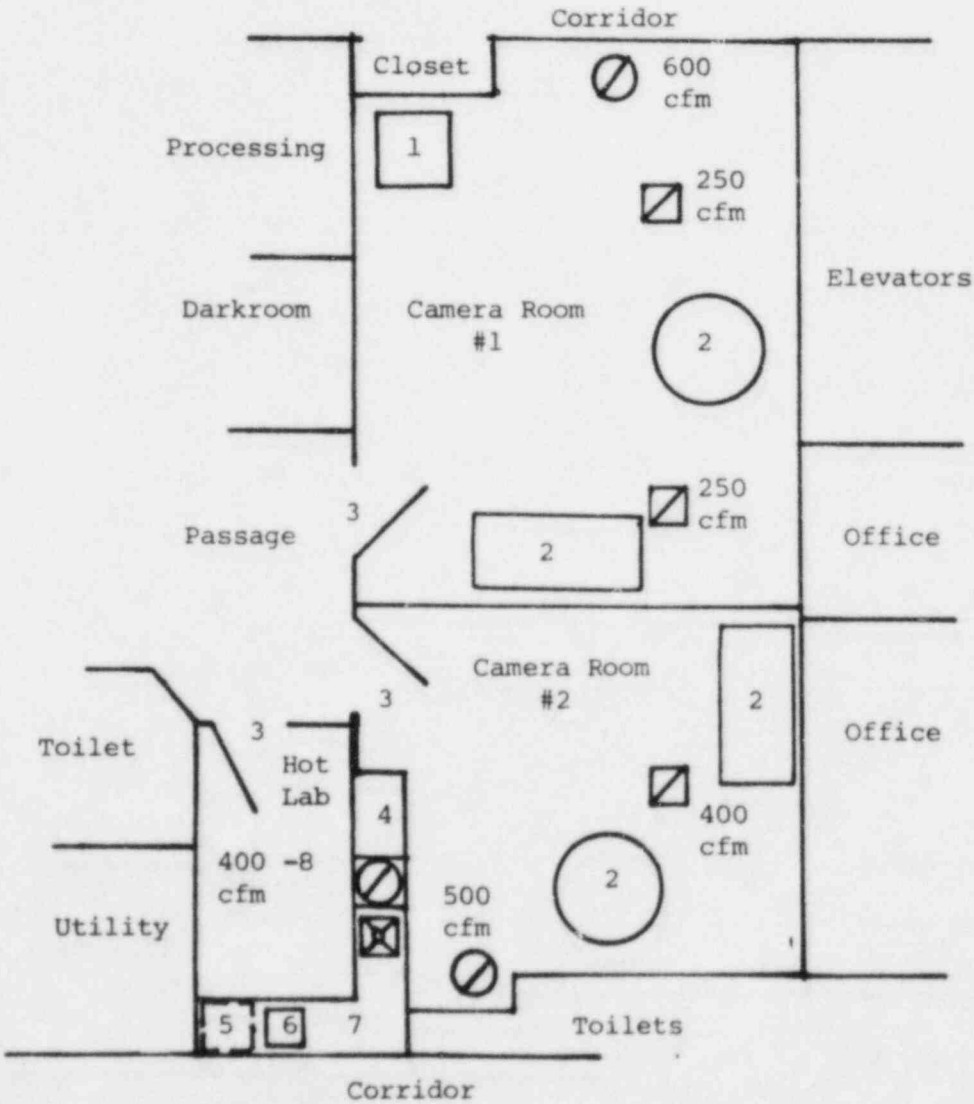
Lead Shielding

5 Lead Bricks
42" L x 30" W x 18" H x 2" T

6 L-Shield
15" L x 12" W x 16" H x ½" T

__ L x __ W x __ H x __ T

__ L x __ W x __ H x __ T




Item #11
1 of 1 pages
Prepared 7/2/85
Lic. #34-04307-02

Item #21

# PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g. Xenon-133)

I. Quantities to be Used:

A. Patient information

1. 10 studies per week
2. 15mCi per patient

B. Possession limit: 300mCi

II. Use and Storage Area:

A. Xenon-133 will be stored in the vented cabinet in the hot lab (see diagram). The cabinet is connected to an independent exhaust system which exhausts the hot lab and camera rooms. The closet will be used to prepare individual doses prior to use. The Xenon will be stored in its original shipping container until used. The same cabinet also is used to store tubing, face masks and etc., that have been contaminated until the Xenon has decayed. Saturated charcoal filters will be stored here also.

The camera rooms are exhausted by this independent exhaust system leading to the exterior rooftop. The camera room exhaust system will be used to discharge all accidentally released Xenon to the outside. The camera room will be used for all patient administrations and for imaging procedures. Either camera room may be used for Xenon studies.

B. The exhaust system for the department is a continuous, independent system. The hot lab and both camera rooms are exhausted by this system directly to the exterior with no recirculation in the hospital. Camera room #1 is exhausted at 600 cfm (500 cfm supply), camera room #2 at 500 cfm (400 cfm supply) and the hot lab at 400 cfm through the vented wall cabinet (no supply).

C. The camera room, the hot lab and the vented wall cabinet are at negative pressure at all times. The ventilation will be checked semiannually with a velometer to assure that no change in exhaust rate has occurred and the rooms are at negative pressure.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III. Procedures for Routine Use:

A. The camera room door will be adjusted so a sensible draft is felt at opening. The patient will be fitted with the rebreathing apparatus and instructed as to the procedure. A trial run will be conducted when possible. The valving and tubing will be examined for continuity. The dose will be prepared and assayed on the dose calibrator. The Xenon will be administered to the patient and three to four views obtained. The gas will be shielded at all times up to patient administration, except during times of transfer from the shielded vial to a shielded syringe (if used). TLD finger badges and whole body film badges will be worn by all occupational personnel involved. Visitors to the nuclear medicine department will be excluded from the camera room during the use of Xenon, unless their presence is required or desired.

B. A Xenon delivery system and charcoal trap, Pulmonex Model 130-500 or equivalent, will be used. Face masks that cover both mouth and nose or nose clamps for use with the mouthpiece delivery systems will be employed to reduce leakage of the Xenon into the camera room.

IV. Accidental Release of Xenon-133:

In order to implement the ALARA philosophy, the accidental release of Xenon into the camera room will result in evacuation of the room for a time period of 20 minutes, if the patient's condition permits. During this time, the concentration will be reduced to less than $1 \times 10^{-5}$ uCi/ml as follows:

A. Camera Room #1:

Room Volume = $3564\ ft^3 = 1.01 \times 10^8$ ml

Initial Concentration ($C_o$) = $\frac{15{,}000\ uCi}{1.01 \times 10^8 ml}$

= $1.49 \times 10^{-4}$ uCi/ml

Clearance Rate ($\lambda$) = $\frac{600\ cfm}{3564\ ft^3}$ = $.168\ min^{-1}$

$$\text{Concentration} = C_o e^{-\lambda t}$$

$$= 1.49 \times 10^{-4}\ e^{-.168 \times 20}$$

$$= 1.49 \times 10^{-4}\ (.0347)$$

$$= 5.2 \times 10^{-6}\ \text{uCi/ml}$$

B. Camera Room #2:

$$\text{Room Volume} = 2295\ \text{ft}^3 = 6.49 \times 10^7\ \text{ml}$$

$$\text{Initial Concentration } (C_o) = \frac{15{,}000\ \text{uCi}}{6.49 \times 10^7\ \text{ml}}$$

$$= 2.31 \times 10^{-4}\ \text{uCi/ml}$$

$$\text{Clearance Rate } (\lambda) = \frac{500\ \text{cfm}}{2295\ \text{ft}^3} = .218\ \text{min}^{-1}$$

$$\text{Concentration} = C_o e^{-\lambda t}$$

$$= 2.31 \times 10^{-4} e^{-.218 \times 20}$$

$$= 2.31 \times 10^{-4}\ (.0128)$$

$$= 2.95 \times 10^{-6}\ \text{uCi/ml}$$

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

V. Air Concentrations in Restricted Areas:

For camera room #2, it is assumed that the exhaust runs at 500 cfm continuously and that 20% of the used Xenon escapes due to leakage, trap pass-through and patient associated losses. It is also assumed that ten studies are performed per week.

Activity (A) = 10 x 15mCi x $10^3$ x 0.2

= 3 x $10^4$ uCi/wk

Volume (V) = 500 cfm x 1.7 x $10^6$ ml/hr/cfm x 40 hrs/wk

= 3.4 x $10^{10}$ ml

Concentration = $\frac{A}{V}$ = 8.82 x $10^{-7}$ uCi/ml

This value is significantly less than the MPC of 1 x $10^{-5}$ uCi/ml. For camera room #1, the average concentration will be less - 7.35 x $10^{-7}$ uCi/ml.

VI. Air Concentrations in Unrestricted Areas:

A. It is again assumed that 20% of the used Xenon will be vented to the exterior. The exhaust from the department runs continuously at 1500 cfm.

Activity (A) = 3 x $10^4$ uCi/wk

Volume (V) = 1500 cfm x 1.7 x $10^6$ ml/hr/cfm x 168 hrs/wk

= 4.28 x $10^{11}$ ml/wk

Concentration = $\frac{A}{V}$ = 7.0 x $10^{-8}$ uCi/ml

This value is significantly less than the MPC of 3 x $10^{-7}$uCi/ml.

B. After every 20 procedures, the trapping efficiency of the charcoal trap will be evaluated by holding a low level G-M on contact with the inlet tube during the equilibrium phase. The probe is then placed on the outlet tube and the maximum reading during washout is noted. If the maximum exhaust reading exceeds 10% of the inlet reading, taking background into consideration, the trap will be considered saturated and the charcoal will be replaced.

C. Saturated charcoal traps will be stored in the vented wall cabinet for decay. After decay, a survey will be performed using a low level G-M on contact with the unshielded column. If the reading is equivalent to background, the column may be disposed. Unused Xenon will be stored for decay or returned to the radiopharmacy. Contaminated tubing, etc. will be surveyed with a low level G-M prior to disposal.