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

Lakeside Clinic
46 W. Shadbolt
Lake Orion, Mich. 48035

TELEPHONE NO.: AREA CODE(313 693 6221

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

same as 1. a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Ray A. Carlson

TELEPHONE NO.: AREA CODE(313 420 0349

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

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. _____
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.)*

David I. Gordon, D.O.

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.)*

David I. Gordon, D.O.

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	X	3.0
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.	X	100

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

NOV 5 1979

Control No. 02455

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
	Supplemant A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or _____ *(Check One)*
	Equivalent Procedures Attached; and
X	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)*	
	Appendix F Procedures Followed; or
X	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)*	
	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		FILM	Landa er	monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	Landauer	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: Institution

(2) LICENSE FEE ENCLOSED: $ 190.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)* Roger W. Murray, D.O.

(2) TITLE

c. DATE 10/26/79

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APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: Victoreen

Manufacturer's model number: 498

Number of instruments available: 1

Minimum range: 0 mr/hr to 1 mr/hr

Maximum range: 0 mr/hr to 1,000 mr/hr

b. Manufacturer's name: Victoreen

Manufacturer's model number: 495

Number of instruments available: 1

Minimum range 0 CPM to 500 CPM

Maximum range 0 CPM to 500,000 CPM

2. Dose calibrator

Manufacturer's name: Victoreen

Manufacturer's model number: 888

Number of instruments available: 1

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Picker	2C
Uptake System	Nuclear Chicago	

4. Other

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.

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% of the calculated or known values for each point checked. Readings within ±20% are considered acceptable if a calibration chart or graph is prepared and attached to 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 _____
Accuracy _____
Traceability to primary standard _____

___ (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 Medical Physics Consultants

(2) Location Ann Arbor, Mich.

(3) Procedures and sources

___ have been approved by NRC and are on file in License No. _____

___ are attached

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Activity (mCi)	Accuracy
Co-57	5.0	5%
Ba-133		
Cs-137	0.200	5%

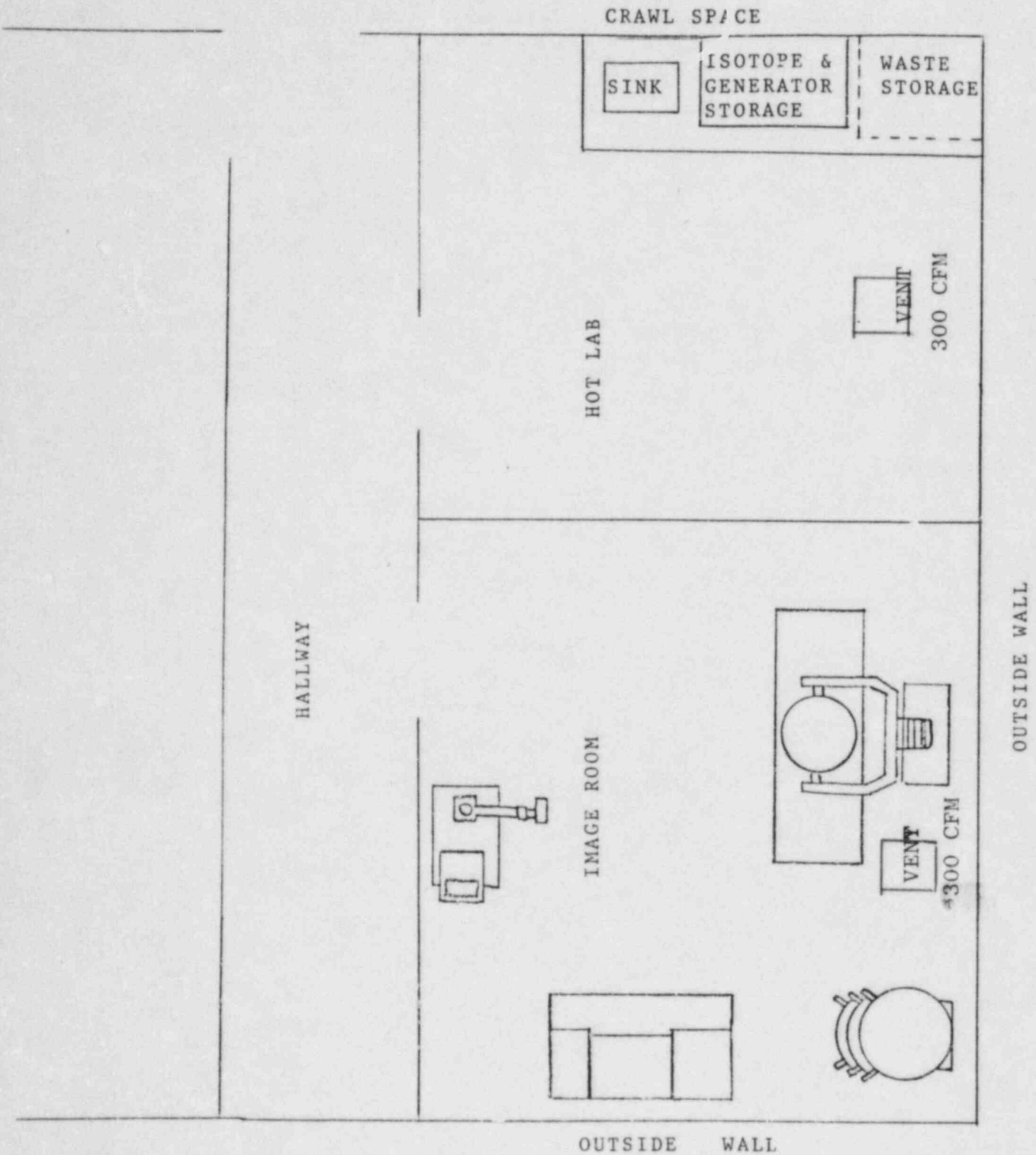
C. X The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

or

____ Equivalent procedures are attached.

*Must be equivalent to the highest activity used.

TH DEPARTMENT IS LOCATED IN E BASEMENT



NOTE: THE WASTE STORAGE AREA IS UNDER THEWORK COUNTER AND IS SHIELDED BY LEAD BRICKS.

Item 12 Personnel Training Program

The training program will be of sufficient scope to ensure that all personnel, including clerical, nursing, housekeeping, and security personnel, receive proper instruction in the items specified in Section 19.12 of 10 CFR Part 19, including:

a. Areas where radioactive material is used or stored.

b. Potential hazards associated with radioactive material.

c. Radiological safety procedures appropriate to their respective duties.

d. Pertinent NRC regulations.

e. The rules and regulations of the licensee.

f. The pertinent terms of the license.

g. Their obligation to report unsafe conditions.

h. Appropriate response to emergencies or unsafe conditions.

i. Their right to be informed of their radiation exposure and bioassay results.

Personnel will be properly instructed:

a. Before assuming their duties with or in the vicinity of radioactive materials.

b. During annual refresher training.

c. Whenever there is a significant change in duties, regul tions, or the terms of the license.

REGULATIONS FOR THE USE OF RADIONUCLIDES

ORDERING:

All radionuclides orders will be placed through the Nuclear Medicine Department. Only those radionuclides present on the authorized list will be ordered, and in quantities not exceeding those specified on this list. A current record of all standing radionuclides orders will be maintained by the Department.

RECEIPT:

The receipt of radionuclides will be recorded by the Nuclear Medicine Department. Any radionuclides received but not ordered, or any errors in activity or form, will be reported immediately to the Radiation Safety Officer. All incoming packages shall be monitored for leakage, comtamination, or damage before opening. If leakage or contamination is found, the NRC will be notified immediately along with the Michigan Health Department and the manufacturer.

CONTROL:

Each radionuclide will be checked to assure accuracy of the:

(a) Activity.

(b) Volume.

(c) Specific activity.

(d) Calibration.

All radionuclides will only be accepted during normal working hours.

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Procedure for Opening Packages
Containing Radioactive Material

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1. Wear Disposable gloves when handling package.

2. Survey package for leakage and contamination using a G-M survey meter and record reading in log book.

   Limits: Surface - 200 mR/hr.
   3 feet - 10 mR/hr.

3. If package is contaminated store immediately in decay storage area to limit spread of contamination and notify radiation safety officer.

4. If package is not contaminated open it and monitor the packing material. Notify radiation safety officer if packing material is contaminated.

5. Store material in appropriate area for use and record in appropriate log book.

APPENDIX J

WASTE DISPOSAL PROCEDURES

1. Liquid Waste will be disposed of

Check as appropriate

____ By commercial waste disposal service (See also No. 4 below)

__X__ In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.

____ Other (specify): _____

2. Mo-99/Tc-99m generators will be:

(Check as appropriate)

_____ Returned to the manufacturer for disposal

__X__ Held for decay until radiation levels as measured 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 disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long-lived radioactive contaminants)

_____ Disposed of by commercial waste disposal service (See also No. 4 below)

_____ Other (specify): _____

_____

3. Other Solid Waste will be:

(Check as appropriate)

__X__ Held for decay until radiation levels as measured 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.

Item No. 18
Date: _____

In support of our request for the use of Xe-133 gas the following information is submitted.

A. Quantities to be used:

1. Estimated number of patients per year is 520, with a dose of 10mCi per patient.
2. The possession limit request is 500 mCi.

B. Use and storage areas:

1. The Xe-133 will be both stored and used in the Department of Nuclear Medicine. The Xe-133 will be stored in the shipping container behind a lead shielded storage area.
2. The ventilation in the area where the Xe-133 will be both stored and used is 300 CFM. The exhaust vents are located in the ceiling and vent directly to the roof.

C. Procedures for routine use.

1. Position patient and set up.
   (a) Single breath - the patient inhales the Xe-133 gas and holds breath during scintigraphy.
   (b) Rebreathing - a rebreathing study is performed through the system until equilibrium is achieved.
   (c) Washout - the Xe-133 is exhaled from the patient and collected in the Xe-133 trap.
2. The Xe-133 gas will be supplied by New England Nuclear or Diagnostic Isotopes, and will be dispensed and collected by the Pulmonex Xenon System model no. 130-500 from Atomic Products Corp.
3. Nose clamps or face masks will be used in order to reduce possible contamination of the air.

D. Emergency Procedures in case of accidental release of Xe-133

1. All personnel and patients will leave the room and close the door.
2. Notify Dr. Gordon.
3. Do not enter the room for a minimum of 10 minutes.

E. Air Concentration of Xe-133 in restricted areas.

1. Maximum amount of activity to be used per week is (A).
2. Estimate of Xe-133 lost during use and storage (f).
3. Volume of air available per week for dilution of the Xe-133 (v) =

$$A = \frac{10 \text{ mCi}}{\text{patient}} \times \frac{10 \text{ patients}}{\text{week}} \times 1X10^{3} \frac{\text{uCi}}{\text{mCi}} = 1X10^{5} \frac{\text{uCi}}{\text{week}}$$

F = assume 25%

$$V = \frac{A \times f}{1 \times 10^{5} \text{uCi/ml}}$$

$$= \frac{1 \times 10^{5} \text{ uCi/week} \times 0.25}{1 \times 10^{5} \text{ uCi/ml}}$$

$$= 2.5 \times 10^{9} \frac{\text{ml}}{\text{week}}$$

The required ventilation rate is

$$\frac{2.5 \times 10^{9} \text{ml/week}}{40 \text{ hrs/week}} \times \frac{1}{1.7 \times 10^{6}} \frac{\text{cfm}}{\text{ml/hr}} = 36.7 \text{ cfm}$$

The actual ventilation in the area is 300 CFM which is greater than the required ventilation for a restricted area.

F. Method of disposal:

1. The Xe-133 will be collected in the model 130-500 Pulmonex Xenon system from Atomic Products Corp.

(a) Maximum amount of Xe-133 to be released per year (A)

(b) Air Flow per year (V)

$$A = 1 \times 10^{5} \frac{\text{uCi}}{\text{week}} \times 52 \frac{\text{week}}{\text{year}} = 5.2 \times 10^{6} \frac{\text{uCi}}{\text{year}}$$

Assume 75% of all Xe-133 is trapped in the system. Therefore

$$A = 5.2 \times 10^{6} \frac{\text{uCi}}{\text{year}} \times 0.25$$

$$= 1.3 \times 10^{6} \frac{\text{uCi}}{\text{year}}$$

$$V = 300 \frac{\text{ft}^3}{\text{min}} \times 1.49 \times 10^{10} \frac{\text{ml/year}}{\text{ft}^3\text{/min}}$$

$$= 4.47 \times 10^{12} \text{ ml/year}$$

$$C = \frac{1.3 \times 10^{6} \text{ uCi/year}}{4.47 \times 10^{12} \text{ml/year}}$$

$$= 2.9 \times 10^{-7} \text{ uCi/ml}$$

2. The trap system will be surveyed at the end of each month to ensure that the trap is working efficiently. A five liter bag will be placed over the exhaust post of the trap. The unit will be operated until the bag is full. The bag will be sealed and placed in front of the gamma camera and counted for one minute. The counts per minute will be recorded and compared with previous readings. A replacement cartridge will be installed whenever there is a significant increase in the monthly CPM. The saturated cartridge will be stored and disposed of in accordance with our disposal procedures.