EXHIBIT A

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 Material 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

Columbus-Cuneo-Cabrini Medical center
2520N. Lakeview Ave
Chicago, Illinois 60614

TELEPHONE NO.: AREA CODE( ) ____ ____

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

Same as 1a
2. Frank Cuneo Hospital
750 W. Montrose, Chicago, 60613
3. St. Francis Cabrini Hospital
811 S. Lytle St. Chicago 60607

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Bashir Pothiawala

TELEPHONE NO.: AREA CODE (312) ~~883~~ ~~6519~~

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. ~~12-12074-01~~
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.)*

Attached

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.)*

Bashir Pothiawala

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
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	700
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	700

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	90
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	30
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	60
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	200
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	400
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	400

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

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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)*
X Names and Specialties Attached; and	X Appendix G Rules Followed; or
X Duties as in Appendix B; or *(Check One)*	Equivalent Rules Attached
Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE	X Appendix H Procedures Followed; or
X Supplements A & B Attached for Each Individual User; and	Equivalent Procedures Attached
X Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	X Appendix I Procedures Followed; or
X Appendix C Form Attached; or	Equivalent Procedures Attached
X 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)*	X Equivalent Information Attached
X Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
X Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	X Appendix K Procedures Followed; or
Equivalent Procedures Attached	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	**20. THERAPEUTIC USE OF SEALED SOURCES**
X Description and Diagram Attached	X Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	X Appendix L Procedures Followed; or *(Check One)*
X 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)**
X 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
X 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	Siemens Gammasonic, Inc.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Siemens Gammasonic, Inc.	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

(2) LICENSE FEE ENCLOSED: $ _____

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

B Pothiawala

(1) NAME *(Type or Print)*
Bashir Pothiawala

(2) TITLE
Radiation Safety Officer

c. DATE
July 18, 1884

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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.

July 18, 1984

Control # 76350

Please refer to our application dated February 15, 1984 for following Items.

Item 4
Item 5
Item 7
Item 8
Item 10
Item 11
Item 12
Item 13
Item 14
Item 15
Item 16
Item 17
Item 18
Item 19
Item 20
Item 21

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APPENDIX C

INSTRUMENTATION

1. Survey meters — Cabrini Hospital

   a. Manufacturer's name: Victoreen

      Manufacturer's model number: 740B

      Number of instruments available: 1

      Minimum range: 1 mR/hr to 25 mR/hr

      Maximum range: 100 mR/hr to 2500 mR/hr

   b. Manufacturer's name: Victoreen

      Manufacturer's model number: 6A

      Number of instruments available: 1

      Minimum range: .01 mR/hr to .5 mR/hr

      Maximum range: 1 mR/hr to 50 mR/hr

2. Dose calibrator

   Manufacturer's name: Squibb Inc.

   Manufacturer's model number: CRC-16

   Number of instruments available: 1

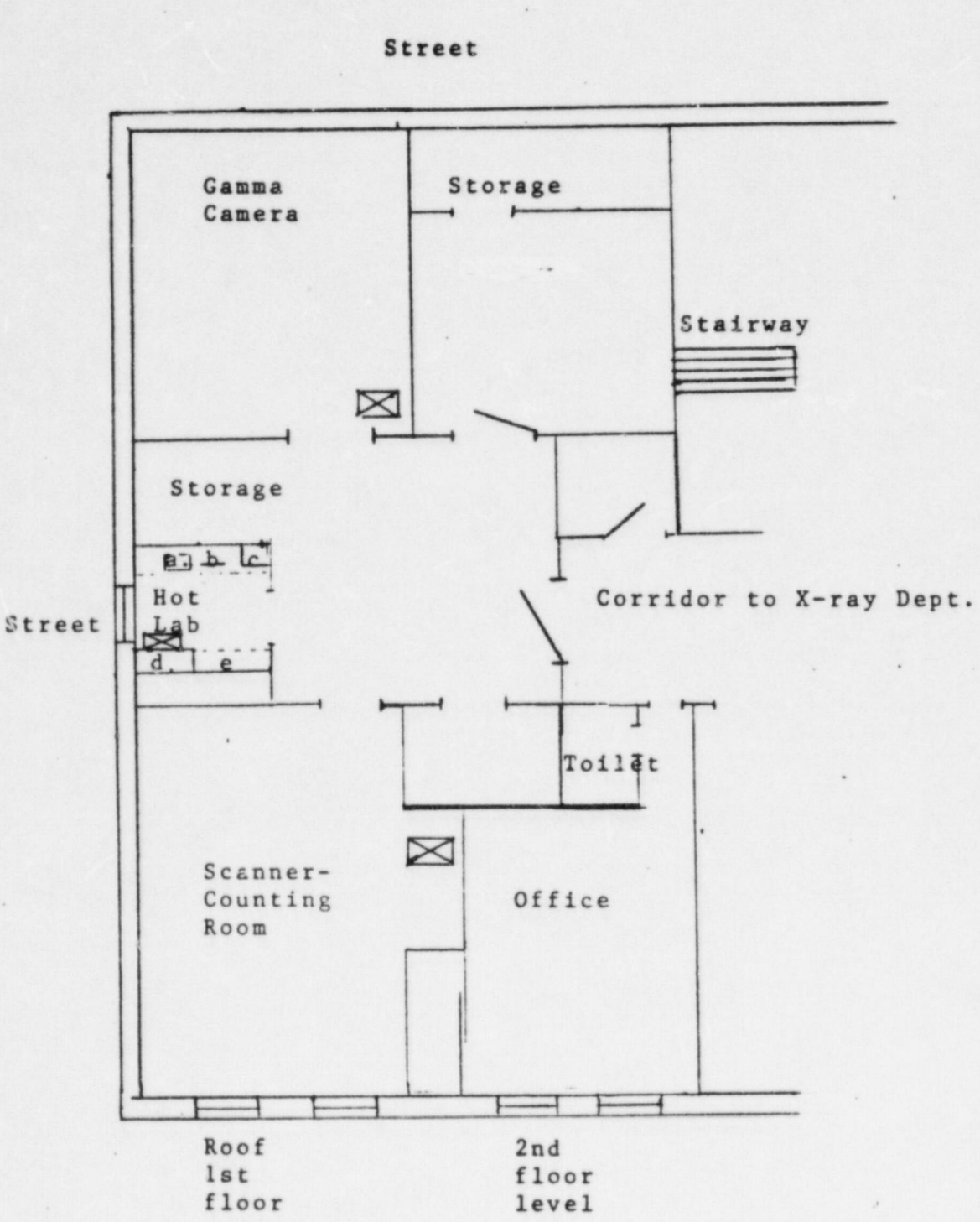
3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Radioisotope dual Probe and well counter	Picker	2852
Gamma Camera	Searle/Nuclear Chicago	30-799
Gamma camera	"	LFOV
Pulmonex	Atomic Pruducts	130-500

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

   Atomic Product Primalert- 50 Continuous Geiger monitor

Cabrini Nuclear Medicine Area -



Hot Lab

a. Dose calibrator
b. "L" shield
c. lead bricks, storage
d. lead bricks, storage
e. sink

Scale: 1" = 8'

⊠ = LOCATION OF EXHAUST

COLUMBUS-CUNEO-CABRINI MEDICAL CENTER

Cabrini Hospital

Weekly Survey Check

Date: _____ Performer: _____

Well Setting: HV = 5.09
LL = 0.50
UL = 0.5
Window - OUT

Well Constancy Check: Source ^{137}Cs

Readings: _____

(Ct/min): _____

Operational Check Cources: _____ mR/hr

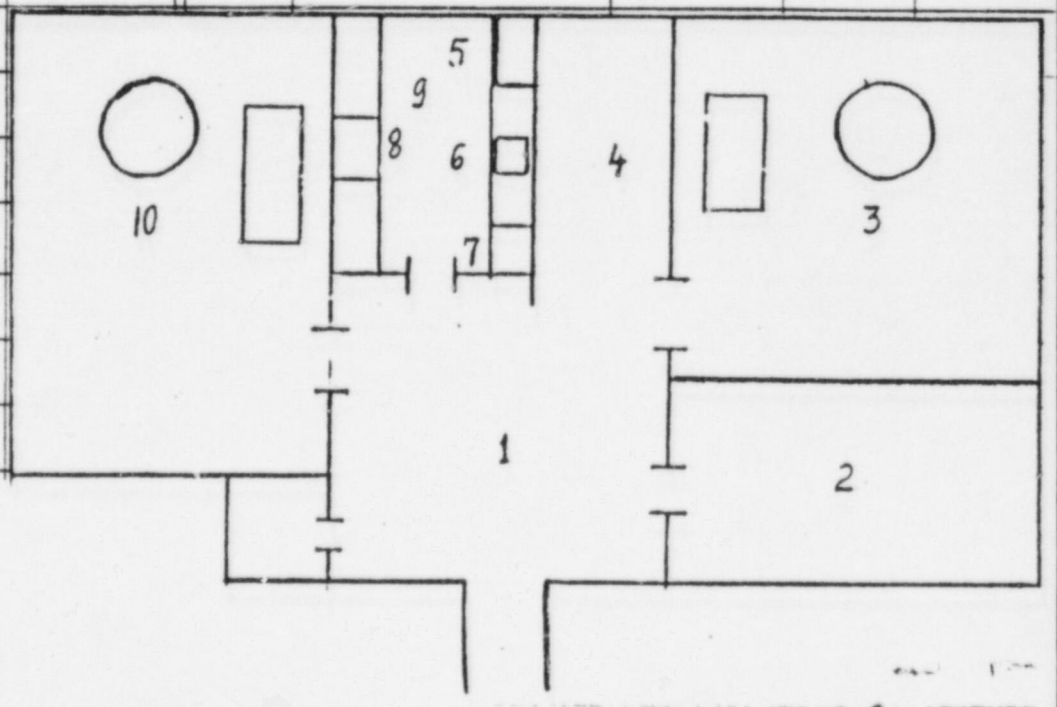
_____ mR/hr

Bkgd: _____ ct/min

MDA: _____ ct/min

Total: _____ ct/min

G. M. Survey			Wipe Tests - ct/min				
No.	Location	mR/hr	No.	Location	Reading	Bkgd	Net
1	Pt waiting area		3-A	Floor			
2	Ultrasound room		5-A	Shld Disp Area			
3	West Camera Room		6-A	Counter			
4	Floor		7-A	"L" Block			
5	Shielded Disp Area		8-A	Sink			
6	Counter		9-A	Floor			
7	"L" Block		10-A	Floor			
8	Sink						
9	Floor						
10	East Camera Room						



ACTION:

Control No. 77196

Cabrini Hospital

XENON-133 PROGRAM

a. Quantities to be used:

1. Maximum number of patients=20 patients per week at an average activity of 10mCi per patient.

2. Desired possession limits= 200 mCi

b. Use and Storage Areas:

1. All Xenon-133 gas is courrier carried and delivered to us in prepackaged dose vials from a supplier. These calibrated vials are shielded in lead tubes (8 HVL's) and stored in our radiopharmacy until needed. The Xenon-133 will be used in our east camera room which has two gamma cameras which can be used for the study. (see diagrams-item 21:)

2. All vents were measured using an Alnor Anemometer (serial no. ECI-26). Three measurements were taken and averaged over the face of the vent. All rooms in the Nuclear Medicine Department have a 0% recirculation rate and this air is exhausted directly to the roof which is exhausted far from windows and intake vents. The east camera room has a measured air exhaust rate of 600 (ft^3/min) cfm and the radiopharmacy has 315 cfm. Our system will maintain Xenon-133 concentrations well below maximum permissible levels.

3. Air flow rates will be monitored and quantitatively checked on an annual schedule. If unusual Xenon-133 background are detected during routine surveys, then the cause will be determined.

c. Procedures for Routine Use:

1) Xenon-133 is purchased in the prepackaged shielded vials which are loaded into a New England Nuclear NRP-186 Calidose dispenser. The radioactive gas is injected into an Atomic Products Corporation (see enclosed information Itam 21: pages 7-11) Pulmonex Xenon System (Model no. 130-500) with a charcoal filter used for trapping most of the Xenon-133 gas. The filter exhaust is being monitored semi-annually to determine at what time the filter should be replaced. The semi-annual check of the system will also evaluate if any leaks are occuring within the system itself.

Monitoring of the charcoal filter is being measured by comparing a known activity and volume of Xenon-133 to that collected from the filter exhaust and other places as needed. The collection bag-valve system collects air samples which are then evaluated by placing the collection system on the uncollimated face of our mobile gamma camera. Backround levels are subtracted to determine the net activity per millimeter of air. When the Charcoal filter approaches the maximum permissible exhaust concentration (1×10^{-5} mCi/ml), it will then be replaced. Spent filters will be sealed and stored for decay and all filters are sufficiently lead shielded for normal handling.

2) Xenon-133 Dispensing System:

Pulmonex Xenon Delivery System-Atomic Products Corporation; Model no. 130-500.

3) In addition to the surveys listed in (c.1) above, most removable joints have clamps attached to prevent leakage. Every reasonable attempt will be made through observation and instruction to the patient to ensure that the gas delivery mask is making an airtight seal before commencing with the Xenon-133 procedure.

d. Emergency Procedures:

See item 21: page 12 for emergency procedures of an accidental release of Xenon-133.

e) Air concentration of Xenon-133 in restricted area:

a) Maximum amount of activity to be used per week

$A = (10\ mCi/pt)\ (10\ pt/wk)\ (10^3 uCi/mCi) = 1 \times 10^5\ uCi/wk$

b) Assume the loss factor during use and storage is

f=20%

c) Minimum required exhaust rate (v) in the area to maintain the Xe-133 concentration below maximum permissible concentration 1×10^{-5} uCi/ml is

$$V = \frac{Axf}{MPC} = \frac{1 \times 10^5 \times .2}{1 \times 10^{-5}} = 2 \times 10^9\ ml/wk$$

Conversion factor 1 cfm = 40 hr/wk x 1.7×10^6 ml/hr-cfm

$= 6.8 \times 10^7$ ml/wk

$$\text{Therefore } V = \frac{2 \times 10^9}{40 \times 1.7 \times 10^6} = 29.4 \text{ cfm}$$

The room is purged at a measured rate of 600 cfm in east camera room and total air flow exhaust rate is 1715 cfm which is well above the required value.

f) Air concentration of Xe-133 in unrestricted area:

1) As mentioned above, the only Xe-133 gas expelled to the unrestricted area is the residue gas of xenon filter through the exhaust vent into the atmosphere. this amount is expected to be minimum.

2) Assume the maximum factor (f) for Xe-133 released during the procedure and storage is
A= 20%

Amount released during a year (A) = 2×10^4 uCi/wk x 52 wk/yr

$= 1.04 \times 10^6$ uCi/yr

MPC in unrestricted area = 3×10^{-7} uCi/ml

$$\text{Required minimum ventillation rate (V)} = \frac{1.04 \times 10^6 \text{ uCi/yr}}{3 \times 10^{-7} \text{ uCi/ml}}$$

3.46×10^{12} ml/yr

Conversion factor 1 cfm = 1.484×10^{10} ml/yr

$$\text{Therefore } V = \frac{3.46 \times 10^{12} \text{ ml/yr}}{1.484 \times 10^{10} \text{ ml/yr-cfm}} = 233 \text{ cfm}$$

The total flow rate of exhaust system of the department is 1715 cfm which is way above the required flow rate of 233 cfm to maintain MPC of 3×10^{-7} uCi/ml.

$V = 1715 \text{ cfm} \times 1.484 \times 10^{10} \text{ ml/yr} = 2.545 \times 10^{13} \text{ ml/yr}$

$$C = \frac{1.04 \times 10^{6} \text{ uCi/Yr}}{2.545 \times 10^{13} \text{ ml/yr}} = 4.08 \times 10^{-8} \text{ uCi/ml}$$

4.08×10^{-8} uci/ml is well below the concentration limit of 3×10^{-7} uCi/ml

Calculation of Emergency Procedure for Xenon - 133

Approximate room size = 15' x 15' x 9' = 2025 ft^3

$$1 ft = 2.832 \times 10^4 \text{ ml}$$

Total ml in the room = $2.832 \times 10^4 \times 2025 = 5.7 \times 10^7$ ml

If one vial accidently reputure or breaks, this would release about 10 mCi

$$\text{Air concentration (Xe-133)} = \frac{10 \text{ mCi} \times 10^3 \text{ uCi/mCi}}{5.7 \times 10^7 \text{ ml}}$$

$$= 1.75 \times 10^{-4} \text{ uCi/ml}$$

Room purge rate of 600 cfm:

$$\text{For one room air turnover} = \frac{2025 \text{ ft}^3}{600 \text{ ft}^3/\text{min}} = 3.4 \text{ min}$$

Using the assumption that 1 complete room purge removes ½ of the activity this would mean that after 4 complete room purges, one would expect 1/16 of the initial concentration to be present. After this period of time, the concentration should be well below 1×10^{-5} uci/ml level.

Evacuation time: 4 x 3.4 min = 13.6 min

the background count will also be performed using the detection equipment in the room.

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COLUMBUS – CUNEO – CABRINI MEDICAL CENTER

DETAIL PROCEDURES

SUBJECT/DEPARTMENT: NUCLEAR MEDICINE		COPY:
DATE ISSUED:	REVISION DATE:	PG OF
APPROVED BY: B. Pothiawala, Medical Physicist		
TITLE: EMERGENCY PROCEDURES FOR AN ACCIDENTAL RELEASE OF XENON-133		NO:

RESPONSIBILITY	ACTION

If an accidental release of Xenon-133 occurs in East Camera Room, then the following steps should be taken:

1) Clear gamma camera room of all patients and personnel

2) Close all entrances, sealing off area.

3) Call the radiation Safety Office (ext. 6517 - 7350)

4) The room should be safe to enter, complying with Section 20.103, 10 CFR. Part 20 (1×10^{-5} μCi/ml) after twenty minutes if only one 10 mCi vial ruptures. If more than 10 mCi are released, contact the Radiation Safety Office. A background level set on a Xenon-133 detection technique can be performed to qualitatively evaluate Xenon-133 concentrations.

5) If a release of Xenon-133 occurs in any other area, close off access and doors to that area and contact the Radiation Safety Office.

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