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 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	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE
Cleveland Metropolitan General Hospital 3395 Scranton Road Cleveland, Ohio 44109 TELEPHONE NO.: AREA CODE (216) 459-4454	
2. PERSON TO CONTACT REGARDING THIS APPLICATION Ernest J. Wiesen TELEPHONE NO.: AREA CODE (216) 459-4454	3. THIS IS AN APPLICATION FOR: *(Check appropriate item)* a. ☐ NEW LICENSE b. ☒ AMENDMENT TO LICENSE NO. 34-03749-10 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.)* Radiation Safety Committee of Cleveland Metropolitan General Hospital	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.)* Ernest J. Wiesen

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	100
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	2000
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	2000

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	100
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	100
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	100
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	50
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	200
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	200

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
Ni -63	Sealed Source	60	Gas Chromatography
Co -57	Sealed Source	10	Instrument Calibration
Hydrogen -3	Sealed Source	150	Gas Chromatography

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24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM	Siemens Gammasonics, Inc.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	Siemens Gammasonics, 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: $ NOT REQUIRED

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
PAUL BUCHSBAUM

(2) TITLE
Associate Vice President

c. DATE
March 13, 1986

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MEMBERS OF RADIATION SAFETY COMMITTEE

Member	Specialty
S. Miron, M.D. (Chairman)	Nuclear Medicine
P. Buchsbaum	Administration
B. Dobyns, M.D.	Surgery & Research
M. King, M.D.	Radiology
K. Pillai	Radiation Physicist
V. Sharan, M.D.	Radiation Oncology
L. Sprague	Radiation Safety Technologist
E. Wiesen	Radiation Safety Officer
V. Dickerson	Nursing

Item #7
March 5, 1986

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: VICTOREEN

   Manufacturer's model number: 490,498

   Number of instruments available: 2

   Minimum range: 0 (490,498) mR/hr to 2 (490) / 1 (498) mR/hr

   Maximum range: 0 (490,498) mR/hr to 200 (490) / 1000 (498) mR/hr

   b. Manufacturer's name: VICTOREEN

   Manufacturer's model number: 440

   Number of instruments available: 1

   Minimum range: 0 mR/hr to 3 mR/hr

   Maximum range: 0 mR/hr to 300 mR/hr

2. Dose calibrator

   Manufacturer's name: CAPINTEC

   Manufacturer's model number: CRC-30

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Siemens	LFOV
Gamma Camera	Siemens	HP IV
Gamma Camera	Picker	DYNA CAMERA
Gamma Camera	Picker	DYNO MO
Uptake Probe	Camberra	SERIES 30

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

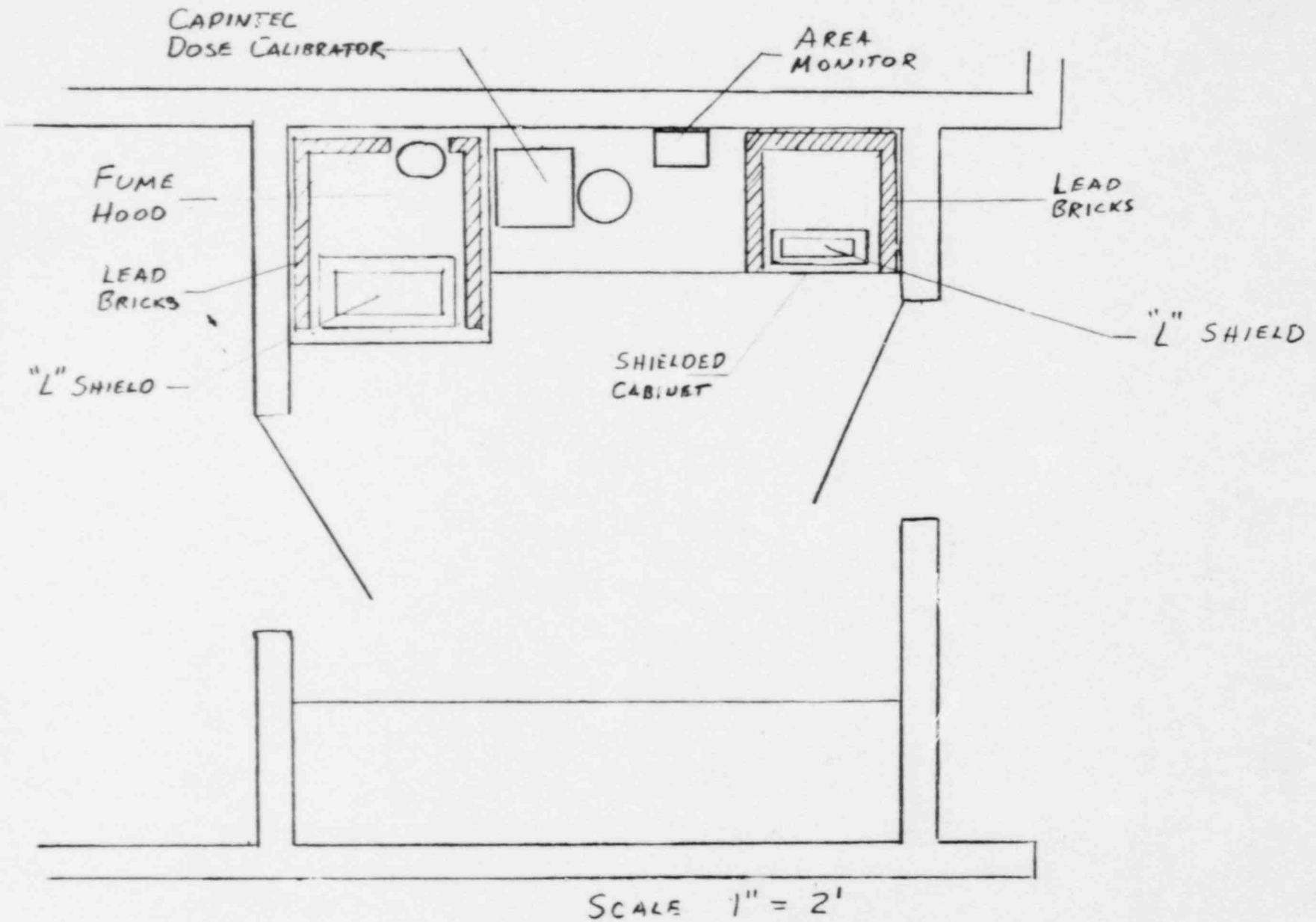
   (2) VICTOREEN Model 495 Area Monitor

ITEM #11: Facilities & Equipment

No generators are used and all of the radioactive material is delivered to the Hospital in individual doses, each in its own syringe and in a lead pig. Most doses remain in the syringes and pigs except when Tc-99m is used with kits. When kits are used, the kit is mixed with individual doses of radioactive Tc-99m behind the lead glass shield in the fume hood. The radiopharmaceutical is then placed back into a syringe, assayed in the dose calibrator, and then immediately placed into a lead pig again. The shielded radiopharmaceutical is carried to the imaging room to be injected. After injection, the empty syringe is then placed in its pig for removal to the "hot room". The imaging room is not used for storage, manipulation or disposal of radioactive material except when in patients. The empty syringes in their lead pigs are returned to the supplier. The new "Hot Lab" is shown in Fig. 1.

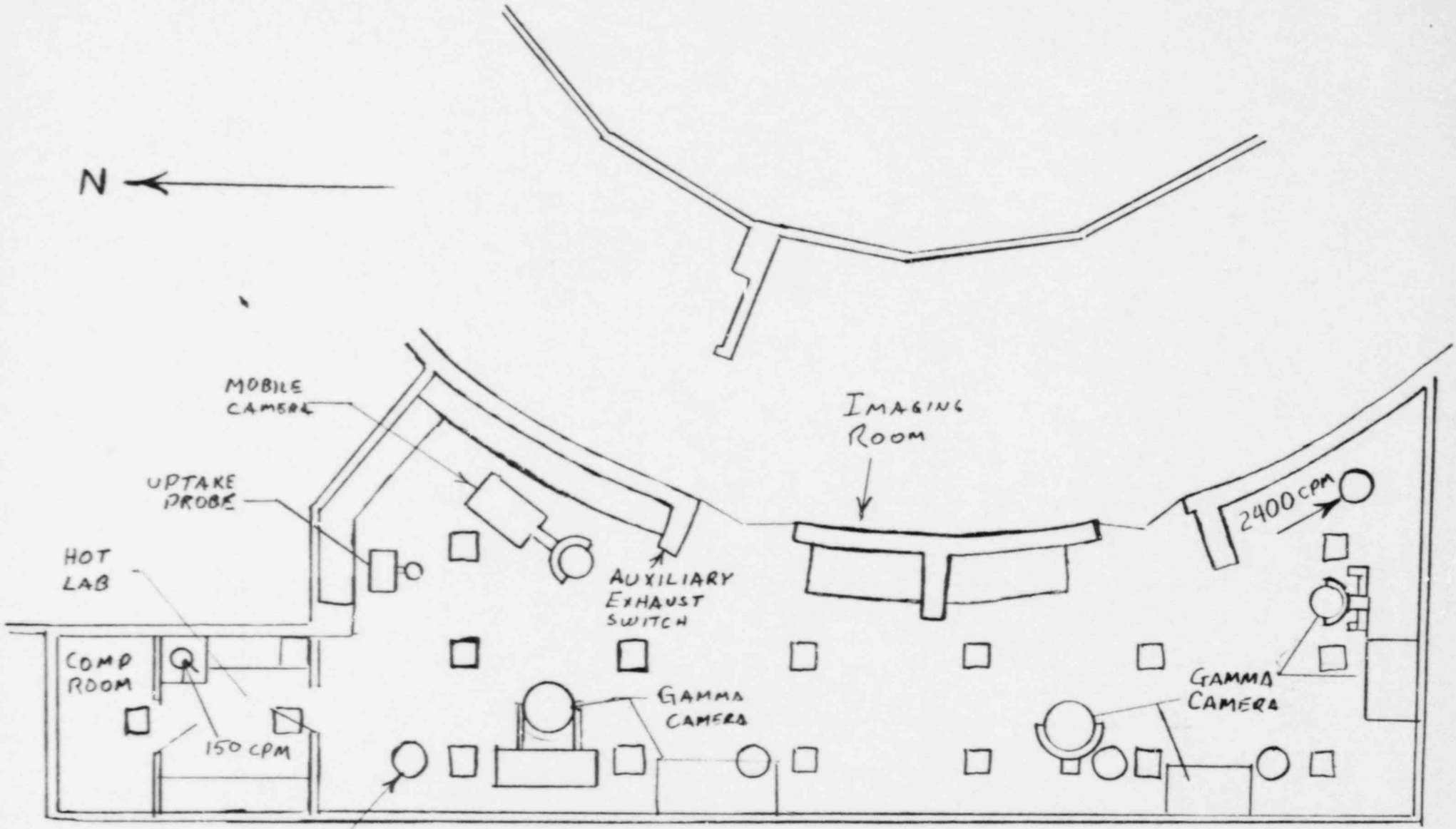
An additional room, outside the Department, is used for decay-in-storage waste. The room is located in a remote area in the sub-basement of the Hospital. The room is primarily used for T-125 decay-in-storage waste and to temporarily store liquid scintillation vials prior to disposal by a commercial firm. The room is continuously locked.

HOT LABORATORY



ITEM #11
MARCH 6, 1986

Imaging Room + Hot Lab.



1/4" = 1'

ITEM #11
MARCH 6, 1986

CUYAHOGA COUNTY HOSPITAL

CLEVELAND METROPOLITAN GENERAL HOSPITAL

XENON-133

1) Quantities to be used.

a. Estimated patient load of 2 per month with an average of 10 mCi of Xe-133 per patient.

b. Possession Limit - 1500 millicuries.

2) Use and Storage Areas.

a. Storage area

1. Hot Lab - see room on attached diagram. The hot lab is completely equipped with lead shield and 2x4x8 lead bricks. The Xenon is obtained from New England Nuclear Corp. and it will be stored in shielded single dose vials as supplied.

2. Imaging room - see on attached diagram. The entire Department is located on the ground floor of the Hospital.

b. Ventilation

1. The Hot Lab has a vent in the fume hood which exhausts at a rate of 100 CPM.

2. The Imaging room has 16 overhead inlet ventilation ducts and one outlet duct with a total air flow of 2400 CPM. For exhaust only, a switch can be thrown which interrupts the conditioned air, creates a negative pressure within the room to exhaust the room at a rate of 600 CPM through four exhaust ducts located in the ceiling.

ITEM #21

March 6, 1986

The percentage of air recirculated will depend upon the outside temperature. The largest amount that can be recirculated to the nuclear medicine lab is 38% and it occurs during the hottest days of summer. During all other seasons, it is less. The flow rate is constant the year round. The Maintenance Department will measure flow rate twice per year to assure that the specified flow rates are maintained.

3. Procedures for routine use.

The Xe-133 in a single dose ampule is placed in a dispenser and injected into a Nuclear Associates "E-Xe-Breathe" disposable Xenon system according to manufacturers instructions. Face masks or mouthpieces with nose clamps will be used to prevent loss of Xe-133 during the study. The exhaled Xe-133 is collected in disposable bags until the study is completed. The bag is then carried and connected to a Radx model 120 xenon trap, and the trap pumps the air from the bag. This model has a built-in saturation detector which gives an aud.o/visual signal when the Xe-133 in the exhaust port reaches 10^{-8}uCi/ml.

4. Emergency Procedures.

In case of accidental release of Xe-133, the following will be carried out:

a. Hot Lab - The room will be evacuated and closed. The room will not be opened until 10 complete air changes

have taken place. The current exhaust system provides 9.3 complete air changes every hour, thus requiring 1 hour and 10 minutes of closure.

b. Imaging Room - The auxiliary exhaust switch will be turned on and the room closed for a period of time required to change the room air 10 times. The current exhaust system provides complete air change in 15 minutes, thus requiring a minimum of 150 minutes.

c. Neither room will be reopened until a radiation survey indicates less than .05 mr/hr.

5. Air Concentration of Xe-133 in Restricted Area.

a. Imaging Room Assumptions

1. .5 patients per week, 10 millicuries per patient for total activity of 5 millicuries per week.

2. Estimate 10% will be lost due to:

a. escape from mouthpiece

b. escape from injection device

c. leakage of rebreathing device

d. leakage due to uncooperative patient

3. Xenon trap activate warning system when the concentration in the exhaust part exceeds 10^{-8}uCi/ml when emptying bag and exhaust is at this level for the 10 minutes required to empty the bag. The trap pumps at 5000 milliliters per minute.

b. Calculation to meet 20.103 of 10 CFR part 20 regulations.

Activity lost per week:

$$.5 \frac{\text{patients}}{\text{week}} \times 10 \frac{\text{millicuries}}{\text{patients}} \times .2 \times 10^{3} \frac{\text{uCi}}{\text{mCi}} = 1000 \text{ uCi/wk}$$

$$.5 \frac{\text{patients}}{\text{week}} \times 5000 \frac{\text{milliliter}}{\text{minutes}} \times 10 \text{ min.} \times 10^{-3} \frac{\text{uCi}}{\text{ml}} = 250 \text{ uCi/wk}$$

TOTAL 1250 uCi/wk

Room air flow rate is 2400 ft^3/min. (Effective flow = 2400 X .62)

$$C = \frac{1250 \text{ uCi/40 hr. wk}}{1490 \text{ CPM} \times 6.8 \times 10^{7} \text{ml/CPM}} = 1.23 \times 10^{-13} \frac{\text{uCi}}{\text{ml}}$$

This is considerably below the requirements in 20.103 of CFR par 20 of 10^{-5} uCi/ml.

6. Absorption of Xe-133 onto Charcoal Trap:

   a. A Radx Model 120 Xenon trap is used to collect the remainder of Xe-133 in the Nuclear Associates "E-Xe-Breathe" bags. The Xe-133 that escapes absorption on the charcoal was included in the calculation in section 5.

   b. The Xenon trap has a GM detector system monitoring the exhaust part of the trap. It is designed in such a fashion that when the unit is first turned on the alarm activates for a few seconds to indicate the system is functional. The alarm is set to activate when the concentration in the exhaust port exceeds $1X10^{-8}$uCi/ml.

   c. Saturated filters will be plugged and placed in storage

until radiation decays to background. Since the filterbecomes saturated over many half-lives of Xe-133, the activity will be very low.

d. The detector alarm system on the Radx Xenon trap will be checked annually after any repair or anytime alarm is triggered. The procedure is outlined in the attached document.

RADX MODEL 120 XENON TRAP

I. Calibration

Experimentally .5 microcuries of Xe-133 in the exhaust tube produce approximately the same number of "beeps"/sec. as a 40 microcurie Cs 137 point source held 11 cm from the GM tube center. The GM detector is installed in the exhaust tube and the Cs 137 held off to the side of the tube. Under these conditions the sensitivity is adjusted to produce an average of 1 "beep" every 2 seconds. The sensitivity graph show the beep rate as a function of activity in the exhaust tube.

To check calibration use a 40 microcurie Cs 137 source as above. If exactly 40 microcuries are not available a source may be placed at an appropriate distance from the GM tube provide the correct radiation level. This distance, S is given by:

$$S = 1.7\ A$$

where A = microcuries of Cs 137 used

II. Dectector sensitivity

low range - approximately 1×10^{-3} microcurie/ml

factory setting: approximately .01 microcurie/ml

III. Dose rate at trap surface

With Xe-133 circulating: less than .05 mr/hr. at any point except intake hose.

In idle condition: approximately 0

IV. Air flow rate from trap: 5 liters/min.

ITEM # 21
February, 1984