Harper Grace Hospitals
Harper Hospital Division

May 24, 1985

William A. Adams, Ph.D.
U.S. Nuclear Regulatory Commission
Region III
Medical Licensing Branch
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: Amendment of 21-04127-02

Dear Dr. Adams:

We wish to amend our Materials License 21-04127-02 by adding an additional usage site for Xenon-133. It is our intention to initiate an evaluation of regional cerebral blood flow in a Special Stroke Unit located on the second floor of the Webber Building, Harper Hospital.

If you have any questions concerning this amendment application or would require additional information, please contact me.

Please find enclosed our original amendment application plus one (1) copy and a hospital check to cover the amendment fee. This check is payable to The U.S. Nuclear Regulatory Commission in the amount of $120.00 as per Title 10 Code of Federal Regulations Part 170.31, 7.B.

Sincerely,

Curtis Smith
Associate Administrator

June - 16 - III

Applicant
Check No. A 93643
Amount/Fee Category $120 (7C)
Type of Fee AMD
Date Check Rec'd 6/20/85
Received By Jacques

CS:ls
enclosures:
(2) applications
(1) check

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U.S. N.R.C.
'85 JUN 20 P2:44
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JUN 14 1985
REGION III

JUN 14 1985
CONTROL NO. 79162

3990 John R., Detroit, Michigan 48201

SPECIAL STROKE UNIT
XENON-133 AMENDMENT
21-04127-02

1. Quantities to be used
   A. Patient information
      (1) 30 studies/week
      (2) 30 mCi/patient
   B. Desired possession limit to be unchanged from present 2.0 curie limit

2. Use and storage areas
   a. Xenon-133 will be used for evaluation of regional cerebral perfusion within the Special Stroke Unit located on the Second Floor, Webber Building, Room 208 of Harper Hospital. A diagram of Room 208 which notes room size, ventilation characteristics, and adjacent areas is attached.

      Receipt, storage and dispensing of unit doses of Xenon-133 will be accommodated through the Nuclear Pharmacy (Hot Lab) Room WG 1132. This area is located within the Division of Nuclear Medicine as indicated in our application dated October 17, 1983. A diagram of this area noting room size, ventilation characteristics, radiation safety features and adjacent areas is attached. We have designed a specially ventilated Xenon-133 storage container to hold all Xenon-133 vials in their original lead shipping containers within the Nuclear Pharmacy until each unit dose is dispensed. A diagram of this storage unit depicting both size and ventilation characteristics is attached.

      Each of the above areas are secured against unauthorized entry via keylocked doors.

   b. Ventilation in all areas where Xe-133 is used and stored is noted below. There is no recirculation of airflow within the ventilation systems noted below.

      Usage Area - Special Stroke Unit

Room	Supply		Exhaust	
208	12"x12"	500 CFM	10"x10"	650 CFM
	12"x12"	500 CFM	10"x10"	650 CFM

      Storage Area - Nuclear Pharmacy

Room	Supply		Exhaust	
WG1132	12"x12"	800 CFM	14"x14"	1,633 CFM
	12"x12"	100 CFM	14"x14"	1,361 CFM

      Xe-133 Storage Container Exhaust = 400 CFM

   c. The exhaust airflow for the Xe-133 storage container is continuously monitored by a Dwyer Magnehelic Air Velocity Meter CAT.#2000-00C. All other areas where Xe-133 is used and stored will be checked via air flow velocity meters semiannually to assure the negative pressure airflow rates noted above.

3. Procedures for routine use

a. The procedures used for routine measurement of regional cerebral blood flow will be those recommended by the manufacturer of the equipment noted below.

b. Instruments for routine use

(1) Dispensing and trapping

Xenamatic Model 4000
Trap efficiency 98%

(2) rCBF Quantitative measurement

Harshaw System 400

(3) Xe-133 room air/gas trap effluent monitor

"XenoGard" Model 36-751

4. Emergency procedures

In case of accidental release of Xenon-133 at the storage or usage area, the entire area will be temporarily evacuated. All doors to the contaminated area will be closed off to allow the ventilation system to exhaust the air from that area. All personnel and patients will remain outside the contaminated area during this period. Taking into consideration room volumes and exhaust rates, each area will remain closed to all personnel to allow adequate room air turnover for the time periods noted below.

Usage Area - Special Stroke Unit

Room 208 = 1600 cu. ft.
Evacuation time = 5 minutes

Storage Area - Nuclear Pharmacy

Room WG-1132 = 1750 cu. ft.
Evacuation time = 2 minutes

5. Air concentrations of Xe-133 in restricted areas

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

$$A = \frac{30 \text{ mCi}}{PT} \times \frac{30 \text{ PT}}{WK} \times \frac{10^3 \text{ uCi}}{\text{mCi}} = 9 \times 10^5 \text{ uCi/wk}$$

f = 10% assumed loss rate

$C = 1 \times 10^{-5}$ uCi/ml N.R.C. Restricted Area Limit

$$V = \frac{9 \times 10^5 \text{ uCi/wk} \times 0.1}{1 \times 10^{-5} \text{ uCi/ml}}$$

$V = 9 \times 10^9$ ml/wk

Required Ventilation Rate

$$V = \frac{\frac{9 \times 10^9 \text{ ml/wk}}{40 \text{ hr/wk}}}{1.7 \times 10^6 \frac{\text{ml/hr}}{\text{ft}^3/\text{min}}}$$

V = 132 CFM

6. Air concentrations of Xe-133 in unrestricted areas

b) Adsorption of Xe-133 onto Charcoal Traps

(1)

$$C = \frac{A \times f}{V} \qquad V = \frac{A \times f}{C}$$

$C = 3 \times 10^{-7}$ uCi/ml = N.R.C. unrestricted area limit

A = 30 mCi/study x 6 studies/day x 5 days/wk x 10^3 uCi/mCi x 52 wk/yr

$A = 4.68 \times 10^7$ uCi used/yr

f = 10% leakage from all sources (conservative estimate)

$$V = \frac{(4.68 \times 10^7 \text{ uCi})(0.1)}{3 \times 10^{-7} \text{ uCi/ml}}$$

$V = 1.56 \times 10^{13}$ ml/year

Minimum required ventilation (exhaust) rate

$$V = \frac{1.56 \times 10^{13} \text{ ml/yr}}{\frac{1.484 \times 10^{10} \text{ ml/yr}}{\text{ft}^3/\text{min}}}$$

V = 1051 CFM

(2) Assurance of collection and trapping efficiency will be monitored on a weekly basis through the use of the XenoCard and the procedure noted below.

WEEKLY GAS TRAP MONITORING

1. To measure the concentration in the effluent from a gas trap, place one end of 1" I.D. hose on the XenAlert's air intake and the other end over the gas trap exhaust port. Gas trap measurements should be made while Xenon is being trapped, such as during the washout phase of a ventilation study.

2. Place the METER MULTIPLIER switch on X1000. Proceed with the washout procedure and observe the MPC meter reading. If it reads less than 100 MPC, place the switch on X100.

3. Determine the activity (A) in the trap effluent by using the

formula: $A = MPC \times 10^{-5} \times V \times T$

where A = effluent activity in uCi
MPC = reading from analog meter

10^{-5} = 1 MPC in uCi/ml.
V = trap flow velocity in ml/minute
T = washout time in minutes

4. Record the results:

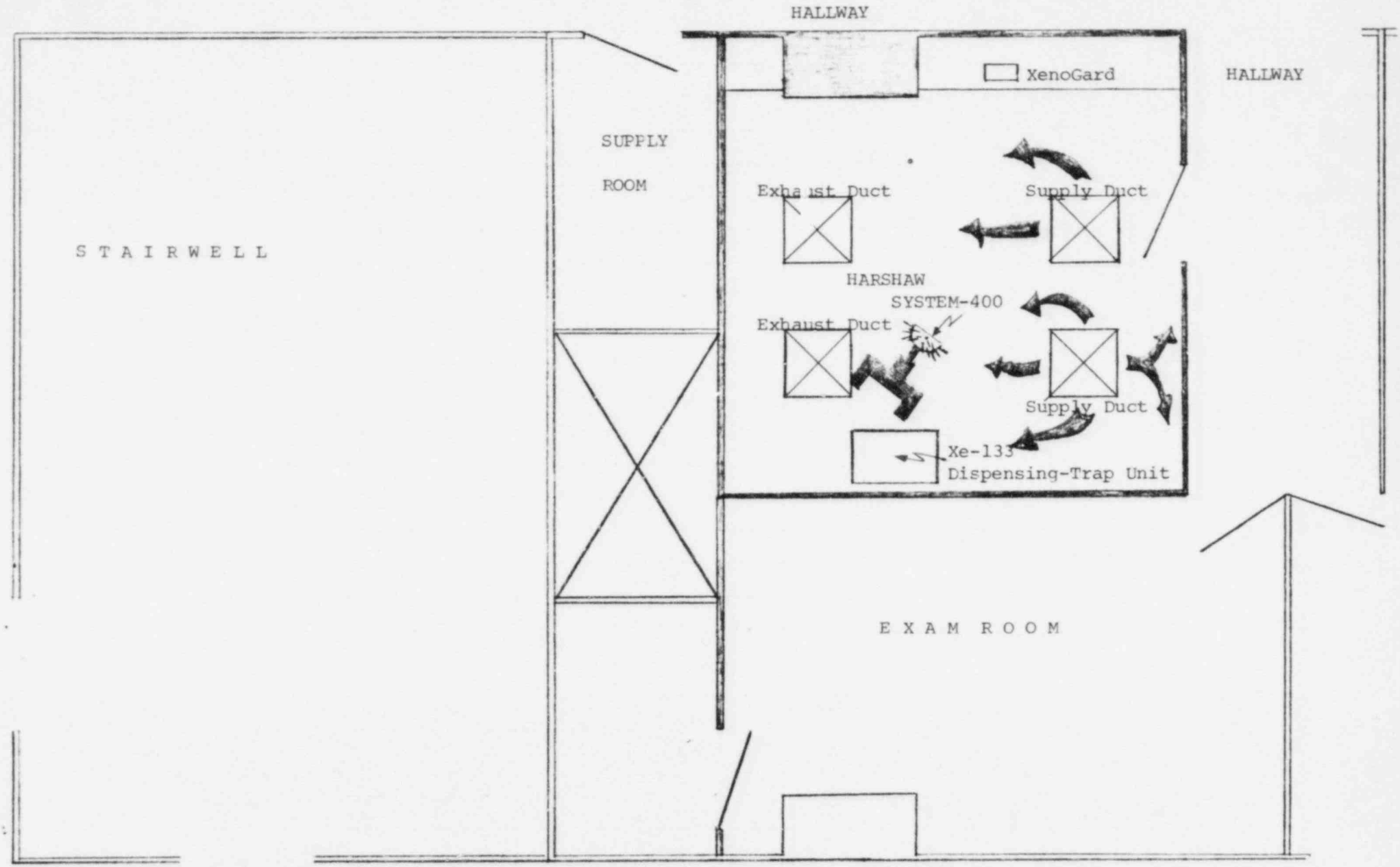
Action level 100-200 uCi/washout (change trap)

(3) Saturated filters are sealed and stored for decay in an area with sufficient ventilation. The average concentration of Xe-133 in air will not exceed that in a restricted area.

(4) We confirm that the XenoGard monitor will be calibrated annually as per the procedure remommended by the manufacturer.

SPECIAL STROKE UNIT ROOM 208 HARPER HOSPITAL

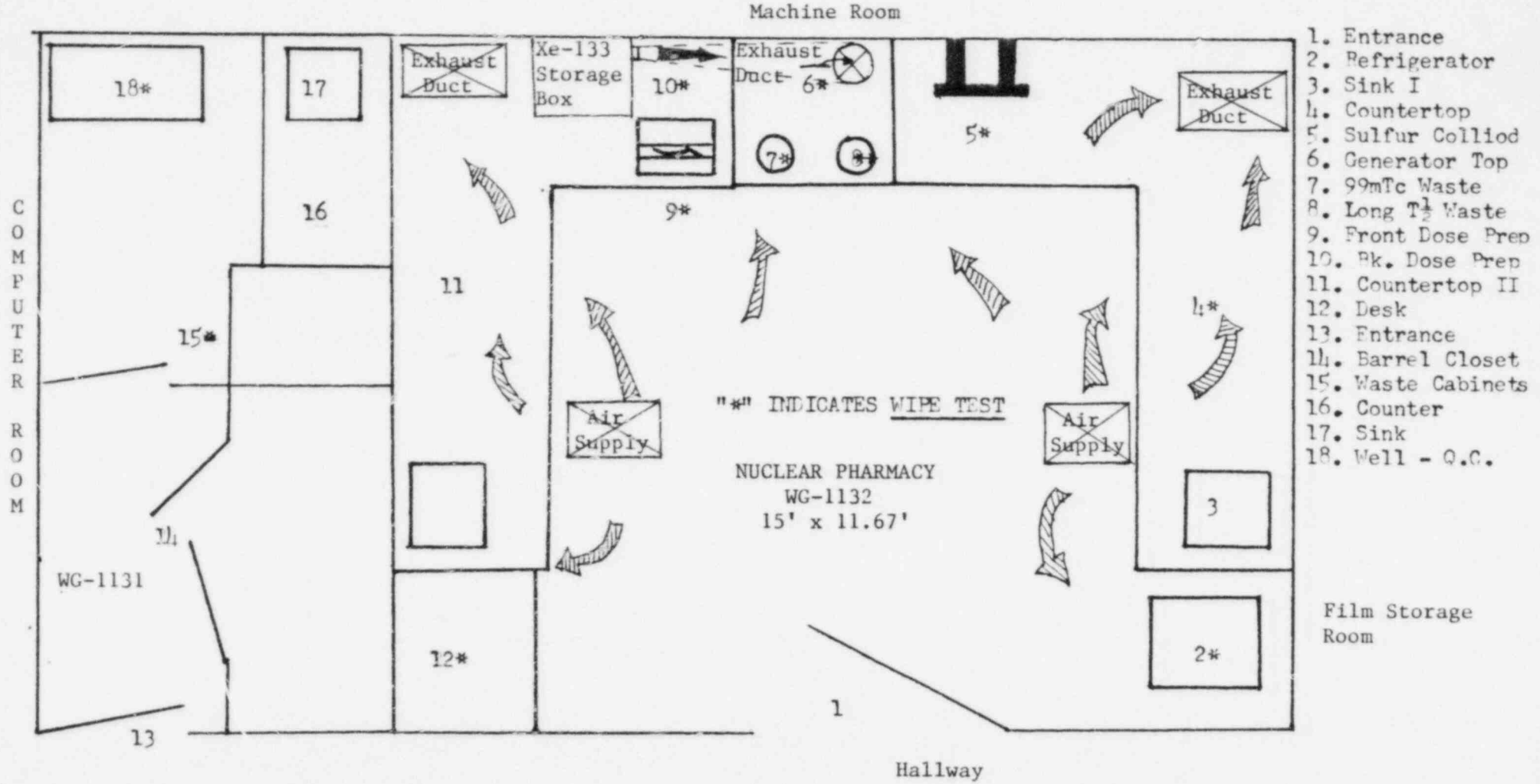
14' x 14'



DEPARTMENT OF NUCLEAR MEDICINE

RADIATION AREA SURVEY

HOTLAB - WASTE ROOMS



1. Entrance
2. Refrigerator
3. Sink I
4. Countertop
5. Sulfur Colliod
6. Generator Top
7. 99mTc Waste
8. Long $T\frac{1}{2}$ Waste
9. Front Dose Prep
10. Bk. Dose Prep
11. Countertop II
12. Desk
13. Entrance
14. Barrel Closet
15. Waste Cabinets
16. Counter
17. Sink
18. Well - G.C.

CONTROL NO. 7 9 1 6 2

Xenon-133 Storage

Cabinet 5/13/85 mc

1' = 1½"

CONTROL NO. 2 9 1 6 2