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U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Ill. 60137

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Gentlemen:

Please amend By-product Material License number 48-07597-01 to include the use of Xenon 133 for use during lung ventilation studies.

1. Quantities to be used

a. Patient Information

- (1) Ten (10) patients per week
- (2) Ten (10) millicuries Xenon 133 per patient

b. Possession Limit - 500 millicuries

(Based on five (5) times weekly use of 100 millicuries $5 \times 100 = 500$)

2. Use and Storage Areas

a. Use Area

Refer to attached diagram of our facility. The Camera Room is 16 x 17 x 8.5 feet (2312 ft³) and is located on the first floor of the hospital.

b. Storage Area

The Isotope Preparation Laboratory is equipped with a 26 x 17 x 12 inch lead brick storage area. Xenon 133 will be stored within this area in the 1/8 inch lead shipping shields. The dimensions of this room are 11 x 5 x 8.5 feet (468 ft³).

c. Ventilation

(1) Use Area

The Camera room has 11 air exchanges per hour for a supply of 575 CFM and an exhaust of 445 CFM.

(2) Preparation Room

The prep room has a supply and exhaust of 115 CFM.

3. Procedure for Routine Use

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Xenon 133 Gas will be procured from a licensed supplier of Xenon 133 in 2 milliliter glass Unit Dose vials in 10 millicurie sizes.

The Xenon 133 Gas will be transferred to a Xenomatic 3000 Controlled Gas Delivery System with a built-in Xenon Trap by a Mallinckrodt Xenomatic Xenon Gas Dispenser.

Face masks will be used to prevent loss of Xenon 133 gas during the patient study.

4. Emergency Procedures

In case of accidental release of Xenon 133 gas, the following procedures will be followed:

a. Camera Room

A damper will be switched on to shut off the supply air. This will also allow the exhaust to continue to operate. Based on an exchange rate of 445 CFM or one exchange every six (6) minutes, the room could be reentered in about 15 minutes or when the radiation level at the floor has reached 0.1 mr/hr (essentially background).

b. Preparation Room

The preparation room has a supply and exhaust of 115 CFM. This room will also not be re-opened until the background level reaches 0.1 mr/hr. or less.

5. Air Concentration of Xenon 133 Gas in Restricted Areas

a. Preparation Laboratory Assumptions

The Unit Dose vials are sealed with rubber stoppers and crimped aluminum closures and are not prone to leakage, however, it will be assumed that there will be a 0.5% loss in the Xenon Dispenser loading procedure.

b. Calculations

$$(1) \text{ Use Rate (A) } = 50 \text{ mCi/wk} = 50,000 \text{ uCi/wk}$$

$$(2) \text{ Loss Rate (f) } = 0.5 \text{ percent}$$

$$(3) \text{ Total Loss (Axf) } = 50,000 \times 0.005 \\ = 250 \text{ uCi/wk}$$

$$\begin{aligned} \text{Air Flow Rate (V)} &= 445 \text{ ft}^3/\text{min} \\ &= 445 \text{ ft}^3/\text{min} \times 60 \text{ min} \times 40 \text{ hr} \\ &= 1.09 \times 10^6 \text{ ft}^3/\text{wk} \\ &= 1.09 \times 10^6 \text{ ft}^3/\text{wk} \times 2.832 \times 10^4 \text{ ml/ft}^3 \\ &= 3.087 \times 10^{10} \text{ ml/wk} \end{aligned}$$

Average Concentration (C)

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$$C = \frac{Axf}{V} = \frac{250 \text{ uCi/wk}}{3.087 \times 10^{10} \text{ ml/wk}} = 0.81 \times 10^{-8} \text{ uCi/ml}$$

c. Camera Room - Assumptions

- (1) It is assumed that the Xenamatic will lose approximately 1% per day by diffusion through the membranes and the Xenamatic is normally loaded with 30 millicuries of Xenon 133 Gas.
- (2) One out of 20 patients will disconnect from the administration apparatus and exhale the entire lung contents into the room.
- (3) The Xenamatic Xenon Trap activates a warning system when the concentration in the exhaust port exceeds 1×10^{-2} uCi/ml. The audio/visual Trap Alarm System will become activated when the adsorption of Xenon 133 reaches the above mentioned level and the charcoal cartridge will be replaced.

d. Calculations

Xenamatic System

- (1) Use Rate (A) = 30,000 uCi in system
- (2) Loss Rate (f) = 1 percent per day
- (3) Total Loss (Axf) = $30,000 \text{ uCi} \times 0.01 \times 5$
 $= 1500 \text{ uCi/wk}$

Patients -

- (1) Use Rate (A) = $10,000 \text{ uCi/patient} \times 10 \text{ patients/wk}$
- (2) Loss Rate (f) = 5 percent of Patient Doses
- (3) Total Loss (Axf) = $10,000 \text{ uCi} \times 10 \text{ pts./wk} \times 0.05 \text{ pats.}$
 $= 5,000 \text{ uCi/wk}$

Xenon Trap -

- (1) Use Rate (A) = 10 patients/week
- (2) Loss Rate (f) = $5 \times 10^3 \text{ ml/min} \times 10 \text{ min} \times (1 \times 10^{-2} \text{ uCi/ml})/\text{patient}$
- (3) Total Loss = $10 \text{ pts./wk} \times 5 \times 10^3 \text{ ml/min} \times 10 \text{ min} \times (1 \times 10^{-2} \text{ uCi/ml})/\text{patient}$
 $= 5,000 \text{ uCi/wk}$

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Total Loss (Axf)_t

$$(Axf)_t = 1,500 \text{ uCi/wk} + 5000 \text{ uCi/wk} + 5000 \text{ uCi/wk}$$
$$= 11,500 \text{ uCi/wk}$$

Air Flow Rate (V): 445 ft³/min

$$V = 445 \text{ ft}^3/\text{min} \times 2.832 \times 10^4 \text{ ml/ft}^3 \times 60 \text{ min/hr} \times 40 \text{ hr/wk}$$
$$= 3.025 \times 10^{10} \text{ ml/wk}$$

Average Concentration (C):

$$C = \frac{(Axf)_t}{V} = \frac{11,500 \text{ uCi/wk}}{3.025 \times 10^{10} \text{ ml/wk}} = 3.80 \times 10^{-7} \text{ uCi/ml}$$

The Camera Room and the Preparation Laboratory are below the Maximum Permissible Concentration (MPC) limit of 1.5×10^{-5} uCi/ml for a restricted area as set forth in Section 20.103 of 10 CFR Part 20.

Method of Disposal

a. Adsorption onto Charcoal Trap

- (1) The Xenamatic has a GM detector system monitoring the exhaust port of the trap. The alarm is set to activate when concentration in the exhaust port exceeds 1×10^{-2} uCi/ml. The exhaust will empty into the camera room and has been considered in previous calculations.
- (2) Saturated filter cartridges will be capped at the input and output ports and placed in the radiation decay storage area for a period of not less than 20 half-lives. Since the cartridge is capped and completely sealed, it is not anticipated that it will contribute to the Xenon 133 air concentration.
- (3) The alarm system of the Xenamatic will be calibrated and tested weekly for proper operation, using the following procedure supplied by the manufacturer.

Alarm Calibration

A functional check may be performed by taking a fairly strong Xe133 source (1-10mCi) and holding it over the dot on the front of the unit. The position of the dot is 9 7/8" over and 6" up from the front, lower left hand corner of the unit.

Calibration is as follows (a minimum 100 uCi source Cs137 source is required):

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1. Place a 100 uCi Cs137 source on the dot at the front of the unit.
2. This should yield a beep every 1-2 seconds.
3. Move the source back about 1" and the beeping should stop.

If your Cs137 source is greater than 100 uCi the following formula may be used:

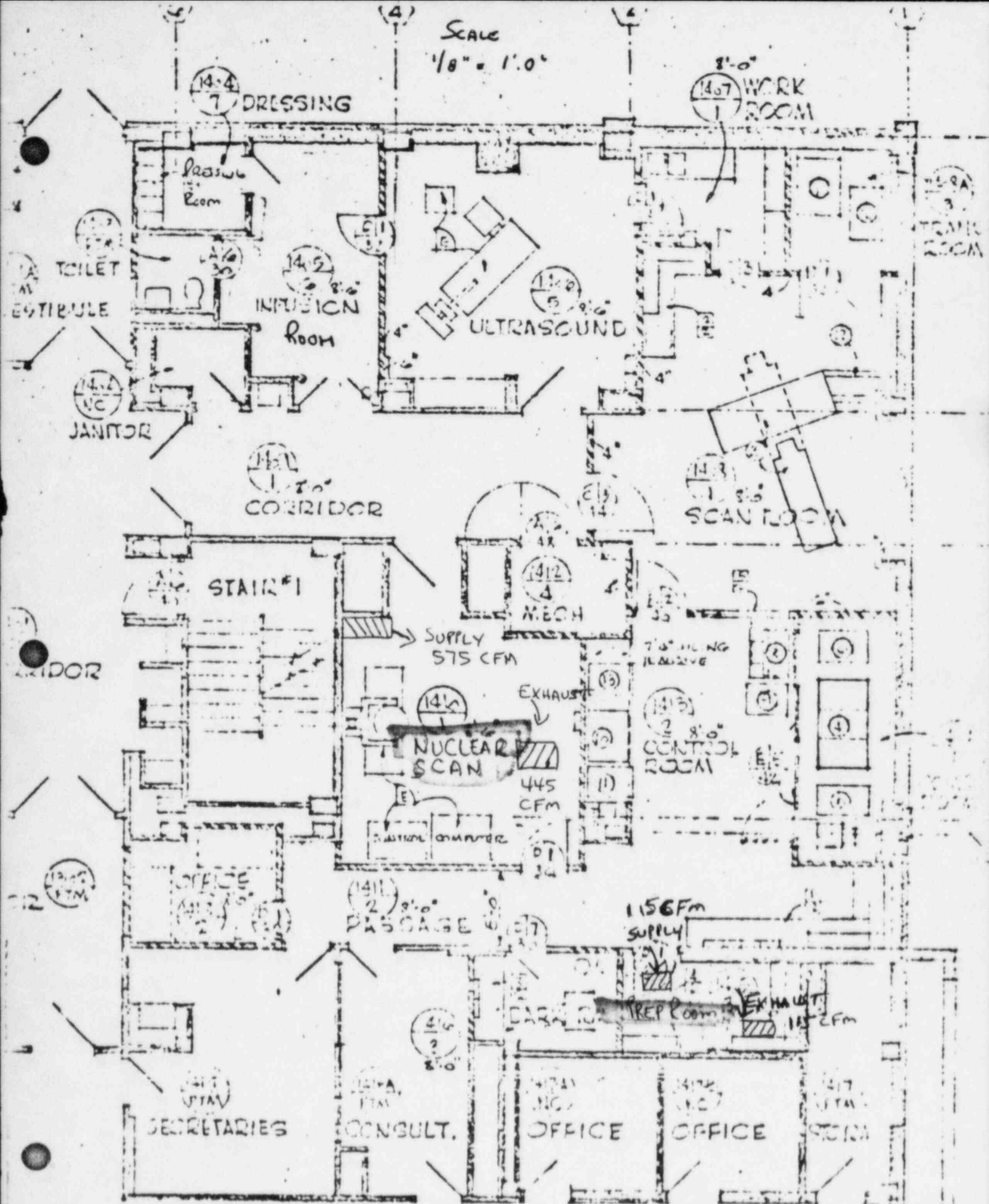
$$\text{Distance from dot} = \sqrt{\frac{\text{Activity of Source}}{100}} (5.9)^2 - 5.9$$

After calculating the distance from the dot move the source back from the dot the calculated distance and proceed as above.

Sincerely,

Thomas J. Grunwald
Technical Director Nuclear Medicine

SCALE
1/8" = 1'-0"



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