DEPARTMENT OF THE ARMY
FITZSIMONS ARMY MEDICAL CENTER
AURORA, COLORADO 80045

REPLY TO
ATTENTION OF

10 SEP 1995

HSHG-PMH

SUBJECT: Request for License Amendment to BML Number 05-00046-13 Concerning Xe-133

THRU: Commander
US Army Health Services Command
ATTN: HSCL-P
~~Fort~~ Sam Houston, TX 78234-6000

Department of the Army
Office of the Surgeon General
ATTN: DASG-PSP-E
5111 Leesburg Pike
Falls Church, VA 22041-3358

TO: US Nuclear Regulatory Commission
Material Licensing Branch
Division of Fuel Cycle & Material Safety
611 Ryan Plaza Drive Suite 1000
Arlington, TX 76011

1. The following information is submitted in support of FAMC's request to amend NRC License 05-00046-13 for changes in use of Xenon-133 (Xe 133).

a. Quantities to be used

(1) Patient information

(a) Average number of studies expected per week = 5

(b) Average activity per patient: 20 mCi

(2) Desired possession limit = 2 Ci

b. Use and storage areas

(1) Areas

(a) Xe-133, as sealed ampules and empty punctured ampules returned from studies, will be stored in the Nuclear Medicine Lab-

oratory fume hood behind lead bricks. A diagram of the Nuclear Medicine Laboratory is attached as Enclosure 1.

(b) Xe-133 will be used for lung function studies in one of two Camera Rooms; number 5, room 132 or number 4, room 136. A diagram of the Nuclear Medicine Service is attached as Enclosure 2.

(2) Ventilation

(a) Ventilation for the fume hood storage area is provided by the fume hood with a measured capacity of 532 cfm. Supply of air is through the laboratory access door.

(b) Ventilation in all cited Camera Rooms is provided by window exhaust fans with a measured capacity of 1139 cfm. Air supply in Camera Rooms 4 and 5 is from the hallway access doors. There is zero recirculation of the exhausted air.

(3) Camera Rooms are maintained under negative pressure by the window exhaust fans. Studies will be conducted only with the fans on and doors opened. The fume hood and these window exhaust fans are evaluated semi-annually.

c. Procedures for Routine Use

(1) Procedures for routine use of Xe-133 are described in the SOP attached as Enclosure 3.

(2) The additional machine to be used to administer and collect Xe-133 is the Atomic Products Pulmonex Xenon System, Model 36-001 or equivalent. A copy of the instruction manual for this machine is attached as Enclosure 4.

(3) The primary procedures used to reduce leakage are

(a) Counseling the patient to obtain maximum cooperation, and

(b) Use of nose clamps at all times unless impossible or inconsistent with the patient's welfare.

d. Emergency Procedures

Emergency procedures in case of accidental releases of Xe-133 are detailed in the SOP, attached as Enclosure 3.

e. Air Concentrations of Xe-133 in Restricted Areas

(1) Maximum activity per week = (10 studies/wk) x (20 mCi/study) = 200 mCi

(2) Estimated fraction of Xe-133 lost from all sources including leakage and inadvertent release $f_1 = 0.20$ $f_2$ = leakage from sealed ampules 0.005/day data from NEN

(3) Volume of air available per week for dilution

(a) Lab fume hood: (532 cfm) x (168 hrs/wk) x (60 min/hr)= $5.36 \times 10^6$ $ft^3$/wk

(b) Each exhaust fan: (1139 cfm) x (40 hrs/wk) x (60 min/hr)= $2.73 \times 10^6$ $ft^3$/wk

(4) Concentration calculations

(a) For the fume hood situation, if 100 mCi maximum were drawn up in the hood with a resultant loss of 20% of the Xenon in the hood and 1 Ci were stored in the hood, $(A_{used} \times f_1 + A_{stored} \times f_2)/V =$ $((100 \times 10^3$ uCi/wk x 0.2) + (1000 x $10^3$ uCi/wk x (0.005) x 7 day/wk))/ $(5.36 \times 10^6$ $ft^3$/wk) $(2.832 \times 10^4$ ml/$ft^3$) = $1.65 \times 10^{-7}$ uCi/ml

(b) For each Camera Room $(A/V) \times f_1 = (1.00 \times 10^5$ uCi/wk) $(0.2)/(2.73 \times 10^6$ $ft^3$/wk) $(2.832 \times 10^4$ ml/$ft^3$) = $2.6 \times 10^{-7}$ uCi/ml

NOTE: No more than 100 mCi/wk will be used in a single Camera Room. The fume hood in (4)(a) above will be operated constantly (168 hrs/wk) to vent any possible leakage of stored radioactive materials. The portion of time the Camera Room fans are to be run will be determined by the calculations above. A running time of eight hours/20 mCi study will be used (see SOP attached as Enclosure 3).

f. Methods of Xe-133 Disposal

(1) Disposal of Xe-133 is accomplished by adsorption onto a charcoal gas trap or equivalent adsorbing medium and storing the saturated filters for decay. The gas trap leakage is included in the 20% overall fraction of loss assumed in e. above. The gas trap will be stored in one of the Camera Rooms cited above.

(2) The service using Xe-133 will evaluate the trapping device initially when a new trapping device is installed or the medium



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is changed and monthly thereafter by collecting the effluent of a typical study in a bag of known volume and counting with a gamma camera without the collimator. Results will be logged and plotted for comparison and analysis by the RPO. The gas trap or medium will be replaced by the user at least semi-annually unless the RPO directs, in writing, a different exchange interval based on comparison and analysis of the user supplied data and the requirements of 20.106 of 10 CFR Part 20.

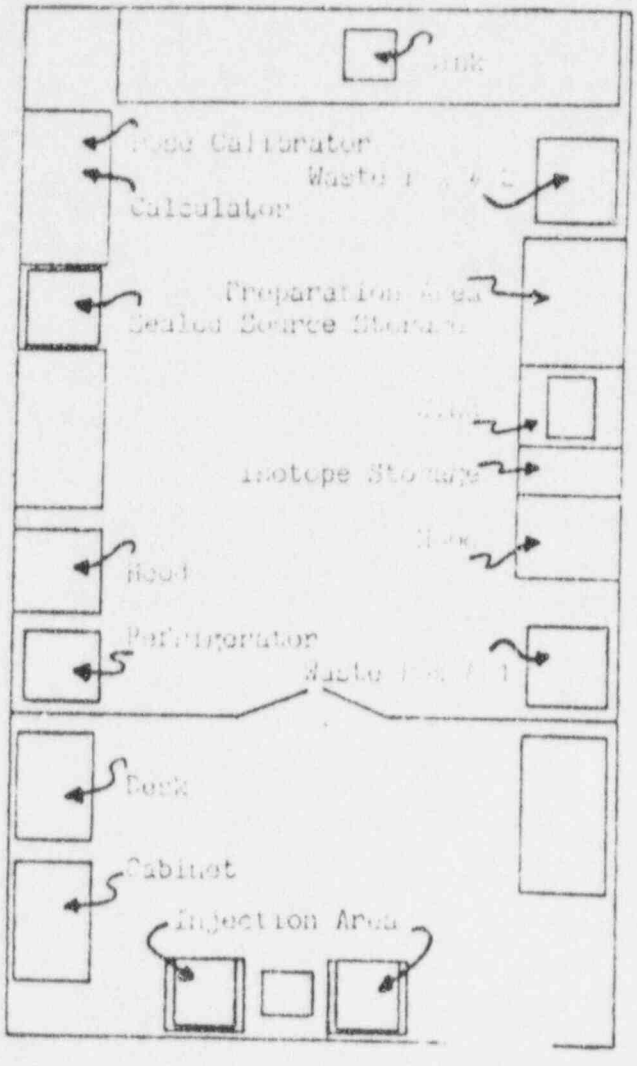
(3) The service using Xe-133 will deliver the saturated absorbing medium (gas traps) to the Waste Lab, Building 603 to Health Physics personnel. The gas traps will be stored for decay in the decay cabinet beneath the fume hood in the Waste Lab, Building 603. The nearest unrestricted/occupied area is separated by one inch lead lining of the cabinet and a solid wall. A diagram is attached (Enclosure 5). Ventilation of the Waste Lab is provided by the fume hood. The ports of the gas traps will be tightly capped in order to minimize leakage. The fume hood provides $1.4 \times 10^4$ $ft^3$/min and is run continuously except for necessary repairs, scheduled maintainance, power failures, and other similar circumstances.

2. If you have any questions, you should contact CPT(P) Dunston at (FTS) 337-4289 or LTC Williams at (FTS) 337-8801.

P.K. Russell

PHILIP K. RUSSELL
Brigadier General, MC
Commanding

5 Encls
1. Diagram (Radiopharmacy)
2. Diagram (Nuclear Medicine Service)
3. SOP for Xe-133
4. Instruction Manual
5. Diagram (Waste Lab)


Sink
Dose Calibrator
Calculator
Preparation Area
Isotope Storage
Hood
Perfusion Pump
Desk
Cabinet
Injection Area

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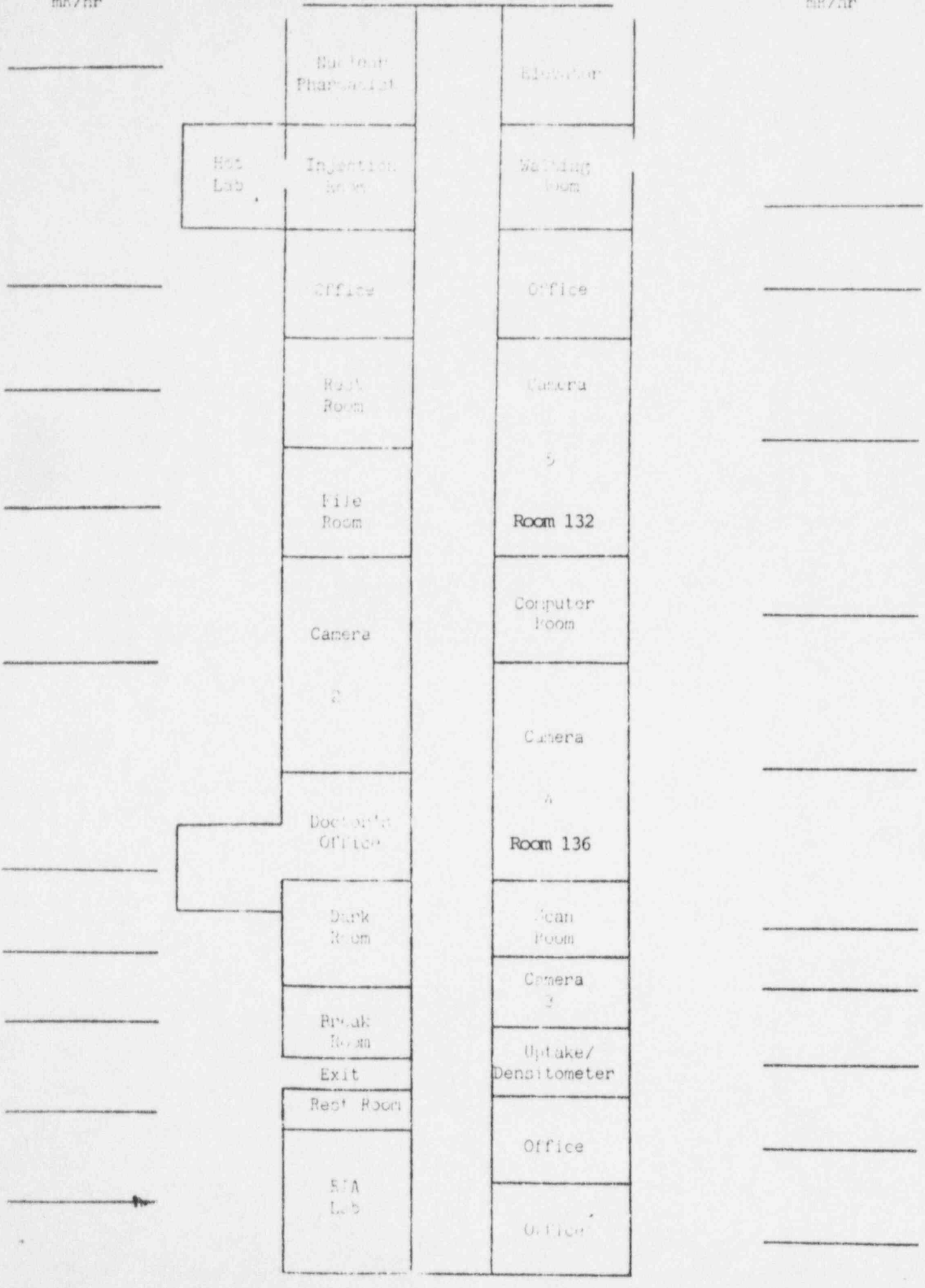
mR/hr

NUCLEAR MEDICINE SERVICE

mR/hr



Nuclear Medicine Service
Standard Operating Policies and Procedures
Xenon-133 Studies

Routine Procedures

1. Dose will be calibrated in the Nuclear Medicine Laboratory prior to the procedure and will be shielded for transport to the camera room.

2. The patient will be counseled thoroughly prior to dose administration, especially regarding the importance of cooperation and not accidentally releasing the gas.

3. Nose clamps will be used whenever possible, consistent with the welfare of the patient.

4. The camera room fan will be turned on before the machine is loaded and will be run for at least an hour nonstop any time a procedure is performed and will run at least eight hours per 20 mCi study.

5. Xe-133 gas trapping devices will be stored only in areas authorized for use of Xe-133.

6. Air conditioners will be off during Xe studies and while the exhaust fans are in operation.

Emergency Procedures

In the event of an accidental release of Xenon in a camera room, the following procedures will be followed:

1. The room will be evacuated by the patient and all personnel.

2. The room will remain vacant with the fan running and door open for at least 30 minutes and will not be unguarded during this time.

3. The RPO (Ext. 4289) will be notified immediately of the release.

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