

**Veterans
Administration**

February 13, 1984

570/114R

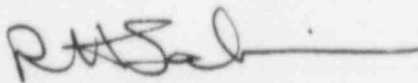
In Reply Refer To:

U.S. Nuclear Regulatory Commission
Materials Licensing Branch
ATTN: Mr. Jim Myers
Washington, D. C. 20555

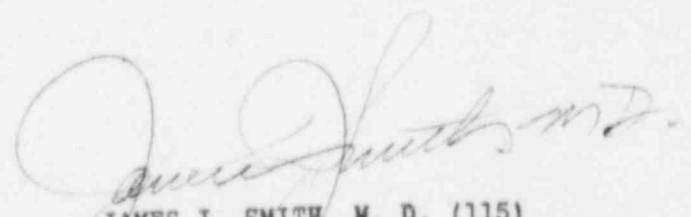
THRU: James J. Smith, M.D. (115)
Director, Nuclear Medicine Service
Veterans Administration Central Office
Department of Medicine & Surgery
Washington, D. C. 20420

SUBJ: Request for NRC License (#04-01935-03) Amendment to Relocate the
Radiopharmacy (Hot Lab).

1. The Nuclear Medicine Service will expand into an area adjacent to the present clinic. Imaging will be carried out within the old and new areas.
2. The service intends to relocate the Radiopharmacy (Hot Lab) from the second floor to the third floor into an area between the old and new imaging areas.
3. Adequate shielding of the new Hot Lab will insure that the exposure rate in areas adjacent to the Hot Lab will be less than 2 mR/hr.
4. The old Hot Lab area will be surveyed and wipe tested in order to demonstrate that no radioactive contamination remains before releasing the area to unrestricted use.
5. A map of the old and new clinic areas and the new Hot Lab area is enclosed.

for 
J. J. MASON
Director

Enclosure


JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

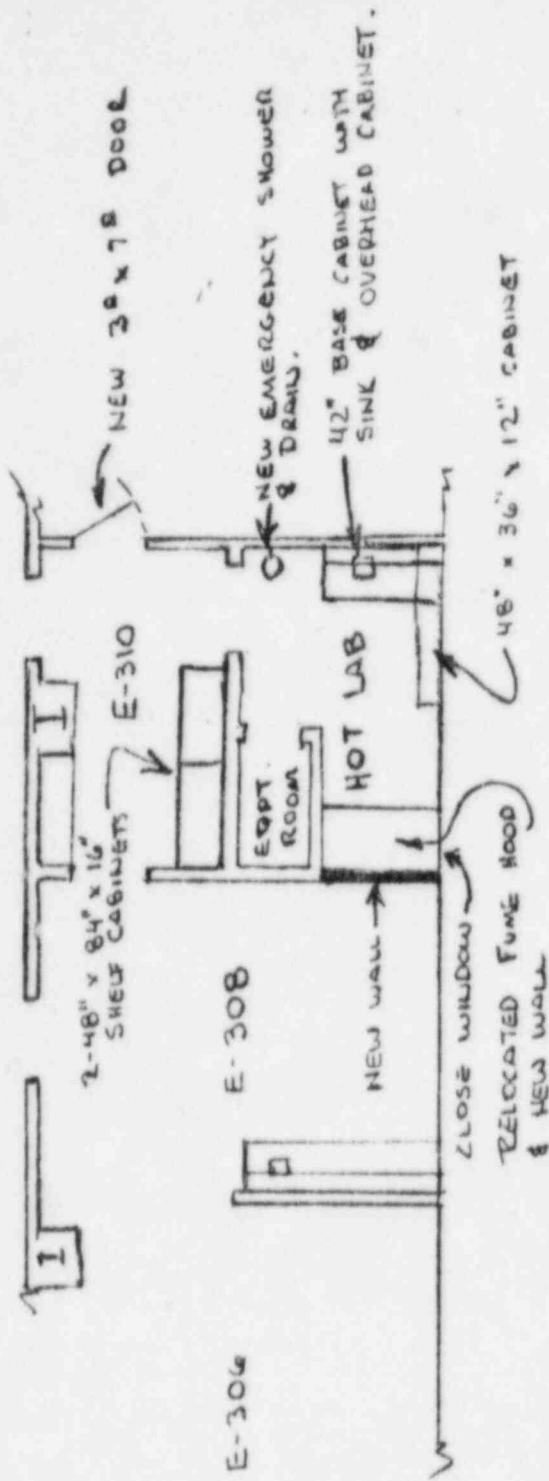
COPY SENT REGION V

8507160203 850520
REG5 LIC30
04-01935-03 PDR

FEE EXEMPT

17215

REMODEL E-310 FOR NUCLEAR HOT LAB SCALE 1/8" = 1'-0"



NOTES:

- 1.- PLASTER WALLS IN HOT LAB TO CONCRETE DECK ABOVE.
- 2.- PATCH TERRAZO & INSTALL VINYL FLOORING.
- 3.- HAMILITE STOVE COUNTER TOPS.
- 4.- REPLACE WINDOW GLASS WITH GLASSWELD, INSULATE & PLASTER OPENING.

HAKEBU-36POL
12-18-83

**Veterans
Administration**

August 15, 1983

In Reply Refer To: 570/114R

See

James J. Smith, M.D.
Nuclear Medicine Service (115)
Department of Medicine and Surgery
Veterans Administration Central Office
810 Vermont Avenue, N.W.
Washington, D. C. 20420

SUBJ: NRC Biproduct Material License #04-01935-03

We request that our NRC Biproduct Material License #04-01935-03
be amended to include XENON-133 as per the enclosed documentation.

[Signature]
J. J. MASON
Director

Enclosure: Documentation of Usage

83 AUG 26 AM 1:00

for *Hein Macdonald*

JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

FEE EXEMPTCOPY SENT REGION V**15712**

Supporting Documentation for Xenon-133 Use

A. Quantities to be Used

1. Estimated number of patients to be studied per year: 520
Average activity per patient: 15 mCi/view x 3 views/patient = 45 mCi/patient.
2. Desired possession limit: 800 mCi (delivered weekly)

B. Use and Storage Areas

1. The ventilation in the Nuclear Medicine Facility (Rooms E-306, 308, 310) has been measured by the VA-Engineering staff and consulting personnel to be at least 200 cfm. There are at least 5 vents located in the Facility. Refer to attached diagram for vent location.

2. Storage areas description: The Xenon-133 will be stored in Nuclear Medicine Radioisotope Mixing Room (W2U3) where the air flow rate has been measured to be about 190 cfm. The Radioisotope Mixing Room has adequate lead shielding and restricted access as necessary for radioisotope use in Nuclear Medicine procedures.

C. Procedures for Routine Use

1. Routine use procedure:

Perfusion Studies: Xenon-133, in aqueous solution, will be injected intravenously. The patient holds his breath during the injection, and when the Xenon reaches the pulmonary capillary bed, it diffuses into the air spaces of the alveoli. The patient will hold his breath for 5 to 10 seconds after the injection and thus intrapulmonary distribution of radioactivity will indicate the regional pulmonary blood flow.

Ventilation Studies: Single Breath; The patient takes a single breath of radioactive Xenon gas and holds his breath for 10-15 seconds. The gamma camera will record the time course of gas flow in the various regions of the lungs. Dead-space ventilation is measured here. Rebreathing; The patient will breathe Xenon gas contained in a closed system. The time required for the radioactivity to reach equilibrium will be related to the efficiency of alveolar ventilation.

2. Special apparatus for administration and collection of Xenon-133: Pulmonex Xenon System, Model 130-500, (see copy of brochure attached).

3. Special procedures to reduce leakage from patient: A patient nose-clamp will be utilized in order to reduce Xenon-133 leakage from the patient into the Nuclear Medicine Facility (see copy of brochure for other details, attached).

D. Emergency Procedures

In case of accidental release of Xenon-133 into the Nuclear Medicine Facility, personnel will be evacuated, outside windows will be opened, and all doors connecting the Facility to other hospital areas will be closed. The Radiation Safety Officer will supervise the monitoring of the radiation level of the Facility and will determine when the radioactivity has been reduced to such a safe level that reoccupancy is possible.

Supporting Documentation for Xenon-133 Use (continued)

E. Air Concentrations of Xenon-133 in Restricted Areas

The Pulmonex system has a Xenon-133 trap that guarantees that essentially no Xenon-133 escapes.

If 10 patients per week is assumed at a Xenon-133 amount of 45 mCi per patient, and at a leakage rate of 25%, then the weekly room leakage is 1.13×10^5 uCi/week. Thus, the required ventilation rate is 170 cubic feet per minute (cfm). Since it has been established that the ventilation rate of the Nuclear Medicine Facility is at least 200 cfm, then the above Xenon-133 leakage is below the NRC limit.

EXAMPLE:

Calculation for Nuclear Medicine Facility use:

A = weekly Xe-133 use

A = 15 mCi/view x 3 views/patient x 10 patients/week

A = 4.5×10^5 uCi/week

f = leakage during use and storage = 25%

V = ventilation = $\frac{A \times f}{1 \times 10^5}$ uCi/ml

using A and f from above

V = 1.125×10^{10} ml/week = 170 cfm

The Xenon-133 leakage and storage will be exhausted through a dedicated ventilation exhaust hood to the roof of a seven-story building. The roof vent is approximately 8 feet above the roof surface and is located well away from air intake vents.

Also, since the leakage rate from the Xe-133 bulk storage unit is essentially zero, then the 190 cfm air flow rate in the Radioisotope Mixing Room should be sufficient for personnel protection.

F. Methods of Xenon-133 Disposal

1. Dilution through exhaust systems: All Xenon-133 processed through the Pulmonex system will be trapped and subsequently allowed to decay. No processed Xenon-133 will be disposed of into the Nuclear Medicine Facility air space.

2. Absorption onto charcoal traps:

a. Handling leakage problem: Leakage with the Pulmonex system is estimated to be less than 1% per day. The Nuclear Medicine Facility has a volume of more than 5000 cubic feet. Also, the air flow is about 200 cfm (see B-2). Thus, the air concentration of Xenon-133 averaged over one year will not exceed 3.03×10^7 uCi per milliliter. The example calculations are:

Supporting Documentation for Xenon-133 Use (continued)

EXAMPLE:

350 mCi (assumed maximum Xe-133 stored on trap)

1% trap leakage/day

$A = 0.91 \times 10^6$ uCi/year

$$V = 200 \text{ cfm} \times 1.49 \times 10^{10} \text{ ml/year} = 3 \times 10^{12} \text{ ml/year}$$

$$C = A/V = \frac{0.91 \times 10^6 \text{ uCi/year}}{3 \times 10^{12} \text{ ml/year}} = 3.03 \times 10^{-7} \text{ uCi/ml}$$

which is below the NRC limit.

b. Trap performance: The Xenon trap exit system will be monitored by a radioactivity detector (see copy of brochure attached). This monitor (detector) will warn the employees of the Facility of any accidental release of Xenon. Also, the monitor will allow an assessment of the trapping efficiency and thus will warn of a trap that should be replaced.

c. Saturated filter handling: Filters which are saturated with Xenon-133 will be stored in an exhaust hood with an adequate lead shield within the Facility. An exhaust fan will ensure that air concentrations of Xenon-133 will not exceed 3×10^{-7} uCi per ml. Once the used filters have their Xenon-133 decayed to a "background" level, then the filters will be disposed of in the common hospital refuse.

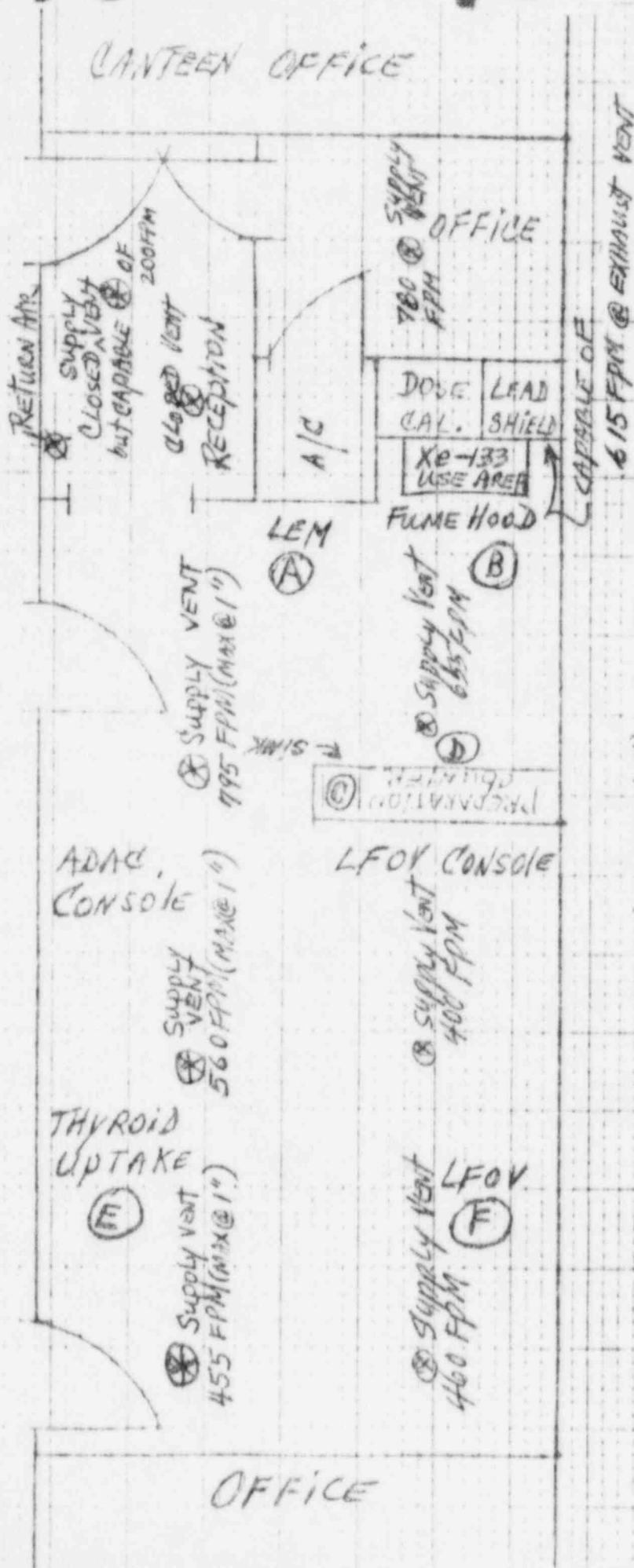
8/83 Air Flow Measurements

VAMC - FRESNO

Nuclear Medicine Rooms E306, 308, 310

APPROX. FONE FOOT

11



OUTSIDE - 2ND FLOOR

TAKEN FROM ENG. DRAWING D-1107

PULMONEX XENON SYSTEM



with integrated
GAS TRAP.

A COMPLETE
FULL FUNCTION
XENON SYSTEM

Atomic Products Corporation

ATOMLAB DIVISION • ESTABLISHED 1949
P.O. BOX 657 CENTER MORICHES, NEW YORK 11934 USA
(516) 878-1074
TWX #510-228-0449

- Complete easy-to-use system.
- "Air-in"/"Air-out" breathing tubes and motor-driven circulator assures resistance-free breathing.
- Two lead glass windows permit observation of patient breathing bags.
- All flow circuits automatically controlled by a master valve system.
- Automatically timed washout.
- Accepts any commercial form of xenon.
- Rolls easily on large casters for positioning of supine or seated patients.
- Fully shielded.
- Carbon dioxide and moisture traps included.

One technician can perform an entire study by simply moving a single handle.

PULMONEX XENON

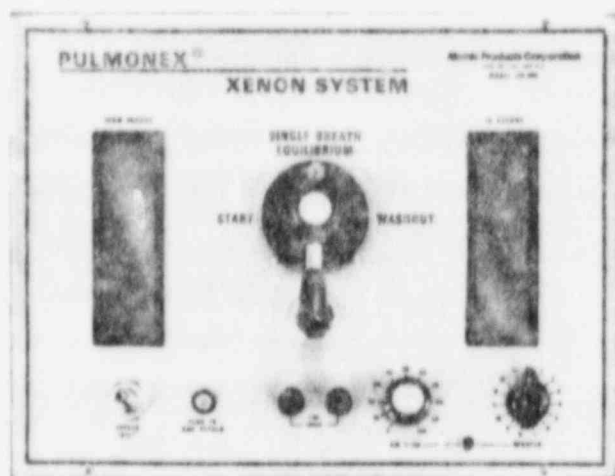
The Pulmonex Xenon System is a simple to use, reliable and complete system for the performance of all regional ventilation studies. A built-in xenon gas trap with disposable charcoal cartridge removes xenon effluent after each study and eliminates the need for expensive venting systems. Motor-controlled air flow assures resistance-free breathing regardless of your patient's pulmonary condition. Practical cabinet design and total mobility permit easy patient positioning in the seated or supine positions.

PULMONEX. .the complete, self-contained xenon system

Pulmonex provides a completely integrated system (delivery unit, and built-in gas trap) for performing xenon studies. A sensitive, responsive master valve, controlled by a single handle on the front panel, and silent synchronized motors permit full-system control of xenon gas flow from initial application to ultimate disposition of the xenon effluent into the gas trap.

All controls are conveniently located on an "up-front" control panel. With the patient on-line, either seated or supine, the user can control the system and observe the patient and gamma camera from one position. The control panel is clearly marked and each mode in the study procedure is distinctively apparent. The two internal patient breathing bags (Air-in and Air-out) are easily observed through individual viewing windows on the front panel. An adjustable manual 15 minute timer initially activates all functions and auto-

matically shuts down the system to complete the study after patient and system washout.



The PULMONEX SYSTEM

The Pulmonex Xenon System effectively integrates manual and electronic controls into a simple, sensitive system that provides maximum, reliable test results using minimum effort. System complexities have been eliminated. All internal circuitry, valves and tubing have been designed to afford ease of operation and patient comfort.

A master valve, controlled by one handle on the front panel, directs the flow of gases throughout the system. Oxygen may be added to the system any time during a study by fingertip button control. A push button operates a circulator blower motor

a breathing.

Full-function xenon delivery system with built-in xenon gas trap for rebreathing, washout, perfusion and single breath studies on supine or seated patients.

Single handle, 3-position control directs all functions for regional ventilation studies.

SYSTEM

to provide gentle positive system pressure. This, combined with a specially-designed master valve and wide diameter, short circuit airways, provides resistance-free patient breathing. There is no dead air space. An injected bolus of xenon reaches your patient exactly when desired. An in-line CO_2 absorber prevents hyperventilation. The system has automatic timer and pressure control dials to accommodate your patient's breathing pattern and to assure complete system washout into the gas trap.

All internal systems are completely shielded for patient and operator safety. A bacteriostatic filter may be used at the mouthpiece to prevent system contamination.

INTEGRATED XENON GAS TRAP

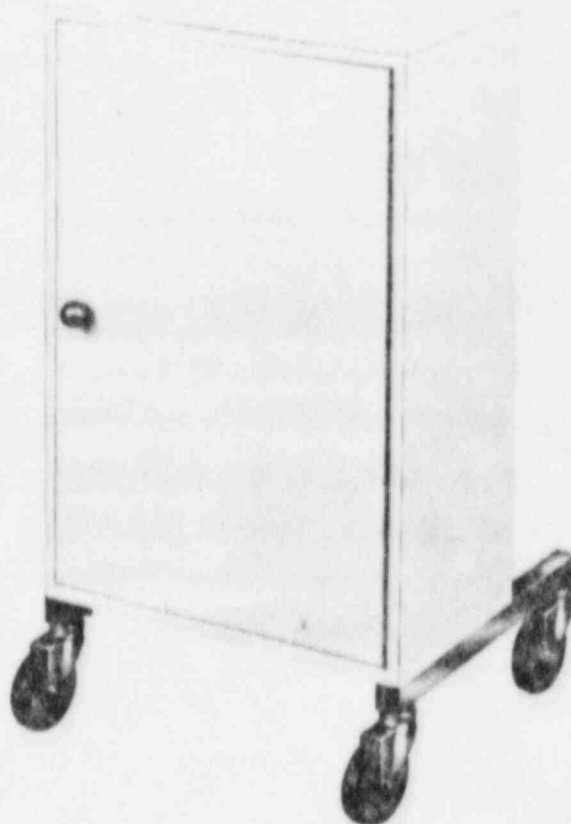
The Pulmonex system has its own built-in gas trap. Exhaled xenon is gently pulled through activated charcoal contained within a "U" shaped cartridge made of 1/8" lead by an induction vacuum pump. The control panel timer and airflow pressure dial regulation of the trap pump assures complete patient and system purging. Only clean air leaves the trap exit port. Under normal usage the charcoal cartridge will last about a year. The gas trap cartridge is easily replaced when expended.

Specifications:

Motor UL approved. 115 VAC, 50/60 Hz.

Size: 18" x 19" x 46"

Weight: 150 lbs.

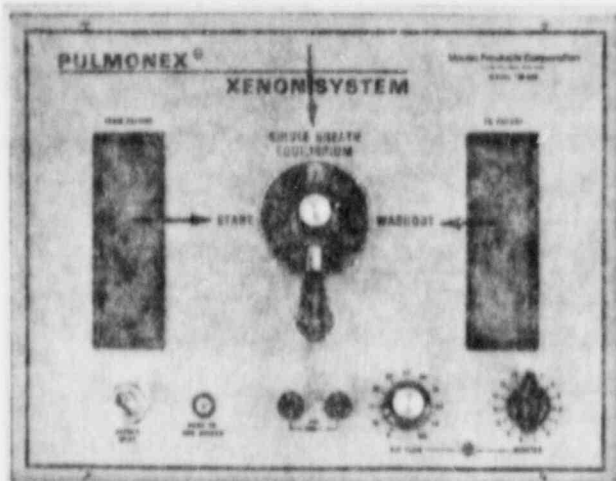


130-500 Pulmonex Xenon System, Complete . . .	\$2725.00
127-318 Disposable Charcoal Cartridge	\$325.00
130-550 Disposable Mouthpiece.	\$1.95 ea
130-700 Disposable Bacteria Filter	\$3.00 ea
139-101 Moisture Absorber (Drierite)	\$7.50 lb.
130-019 Soda Lime, CO_2 Absorber	\$4.25 lb.

PULMONEX XENON SYSTEM

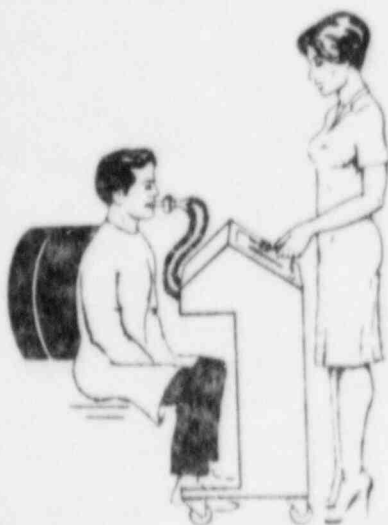
SIMPLE, SAFE OPERATION

There are only three valve positions.



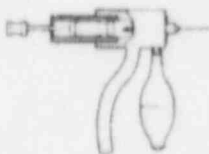
Position 1

Start: Patient breathes room air
System is charged with O_2



Position 2

Single breath and equilibrium
imaging.



- This is when you add Xe, either a bolus or a homogeneous mixture.
- An in-line CO_2 filter prevents hyperventilation.
- When the patient equilibrates, switch the handle

Position 3

Washout

- The patient is now breathing room air from a one-way valve through the delivery system and into the built in Gas Trap. During washout, the Gas Trap is activated. A pump draws the patient's expired breath through a purifying bed of activated charcoal. The Xenon is stripped away and only clean air leaves the Trap exit port.



Atomic Products Corporation

Center Moriches, New York 11934, U.S.A.
(516) 878-1074

XENALARM XENON TRAP MONITOR

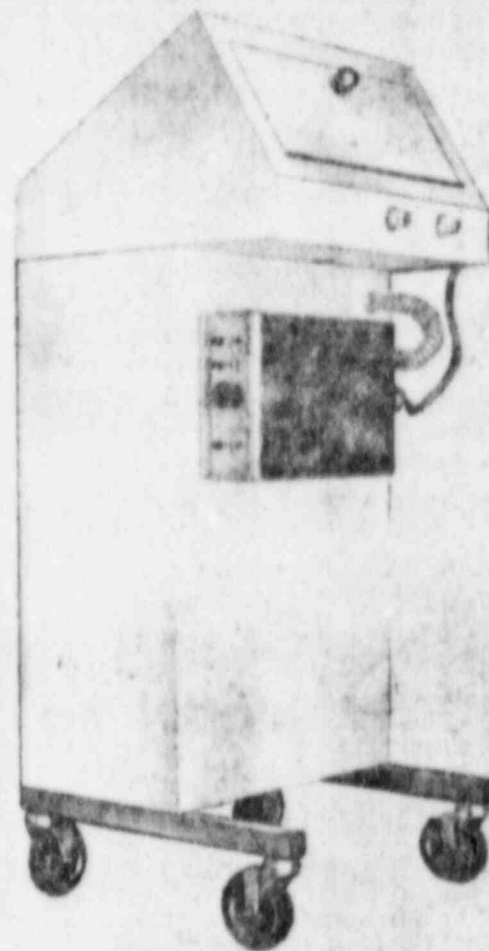
- Simple, sensitive, compact unit immediately alerts user to excess concentrations of radioactive xenon.
- Visual and aural alarms.



Placed at the exhaust port of any xenon gas trap, the Xenalarm monitors the xenon exhaust level and automatically trips a visual and aural alarm when concentrations of radioactive xenon exceed 1×10^{-2} uCi/ml. NRC and State agencies require that the xenon concentration in controlled areas does not exceed 1×10^{-5} uCi/ml averaged over one year based on a 40 hour work week. Xenalarm allows an exhaust rate in excess of the limit as the exhaust is diluted in the room and still further diluted by virtue of the required room ventilation.

The detector is a sensitive end window G-M tube inserted directly in the exhaust stream. The system measures both beta and gamma emissions of xenon.

A "beeper" audio alarm and a flashing red light warn of excessive radioactive xenon. The audio alarm may be turned off at any time by a simple "off-on" switch. Should the alarm activate during or after a study, the charcoal cartridge in the trap should be changed immediately after the completion of the study.



The "Test" button permits manual activation of the alarm system to ascertain its operation. method to calibrate the unit with a known 137 source is provided.

The complete unit measures 8-1/2" W x 3-11/16" H x 13-3/16" D.

136-250	Xenalarm Xenon Trap Monitor, 110V	\$ 795.00
136-257	Xenalarm Xenon Trap Monitor, 230V	\$ 895.00

15712

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JUL 7 1982

NUCLEAR MEDICINE SERVICE
(115)Veterans
Administration

June 29, 1982

In Reply Refer To: 570/114

To: Material Licensing Branch
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Thru: James J. Smith, M.D. (115)
Director, Nuclear Medicine Service
Veterans Administration Central Office
Department of Medicine and Surgery
Washington, D.C. 20420



SUBJ: Amendment #21 to NRC License No. 04-01935-03.

1. In License 04-01935-03, Item 11, page 5, a diagram of the RIA Laboratory is shown.
2. Because of seismic reconstruction in/around the present RIA area, we will temporarily move the RIA Laboratory into the adjacent Room W2U2. This room formerly was used as the Nuclear Medicine Imaging area, but was deactivated as per Amendment No. 19. We will post appropriate signs in accordance with 10CFR 20.203.
3. Surveys and wipe tests of the former RIA area indicated that this area is uncontaminated and thus can be used for unrestricted use. (Wipe test results are attached).

for J.J. MASON
Director

Enclosures

FEE EXEMPT

JAMES J. SMITH, M.D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

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INSPECTION AND ENFORCEMENT

8409270663 3pp



RADIATION DETECTION COMPANY

162 Wolfe Road • P.O. Box 1414 • Sunnyvale, California 94088 • (408) 735-8700

RADIOACTIVE SOURCE LEAK TEST REPORT

Report Number 3

Made for: Veterans Administration Hospital
Attn: Donald Holmes
2615 Clinton Ave.
Fresno, CA 93703

Purchase Order No.

The following samples submitted to Radiation Detection Company for analysis were collected on

RDC No.	Isotope	Activity	Model No.	Serial No.	Nanocuries*	
					Alpha	Beta-Gamma
75609	Am-241/Cs-137			RI-1	< 0.005	< 0.005
75610	Am-241/Cs-137			RI-2	< 0.005	< 0.005
75611	Am-241/Cs-137			RI-3	< 0.005	< 0.005
75612	Am-241/Cs-137			RI-4	< 0.005	< 0.005
75613	Am-241/Cs-137			RI-5	< 0.005	< 0.005
75614	Am-241/Cs-137			RP-1	< 0.005	< 0.005
75615	Am-241/Cs-137			RP-2	< 0.005	< 0.005
75616	Am-241/Cs-137			RP-3	< 0.005	< 0.005
75617	Am-241/Cs-137			RW-1	< 0.005	< 0.005
75618	Am-241/Cs-137			RW-2	< 0.005	< 0.005
75619	Am-241/Cs-137			RW-3	< 0.005	< 0.005
75620	Am-241/Cs-137			CONTROL	< 0.005	< 0.005

Source Number none is considered to be leaking.

*The presence of less than 5 nanocuries (0.005 microcuries) of removable contamination from leak tests is acceptable to the Department of Health, State of California and the Nuclear Regulatory Commission.

Analyst: Harold B. B. B.

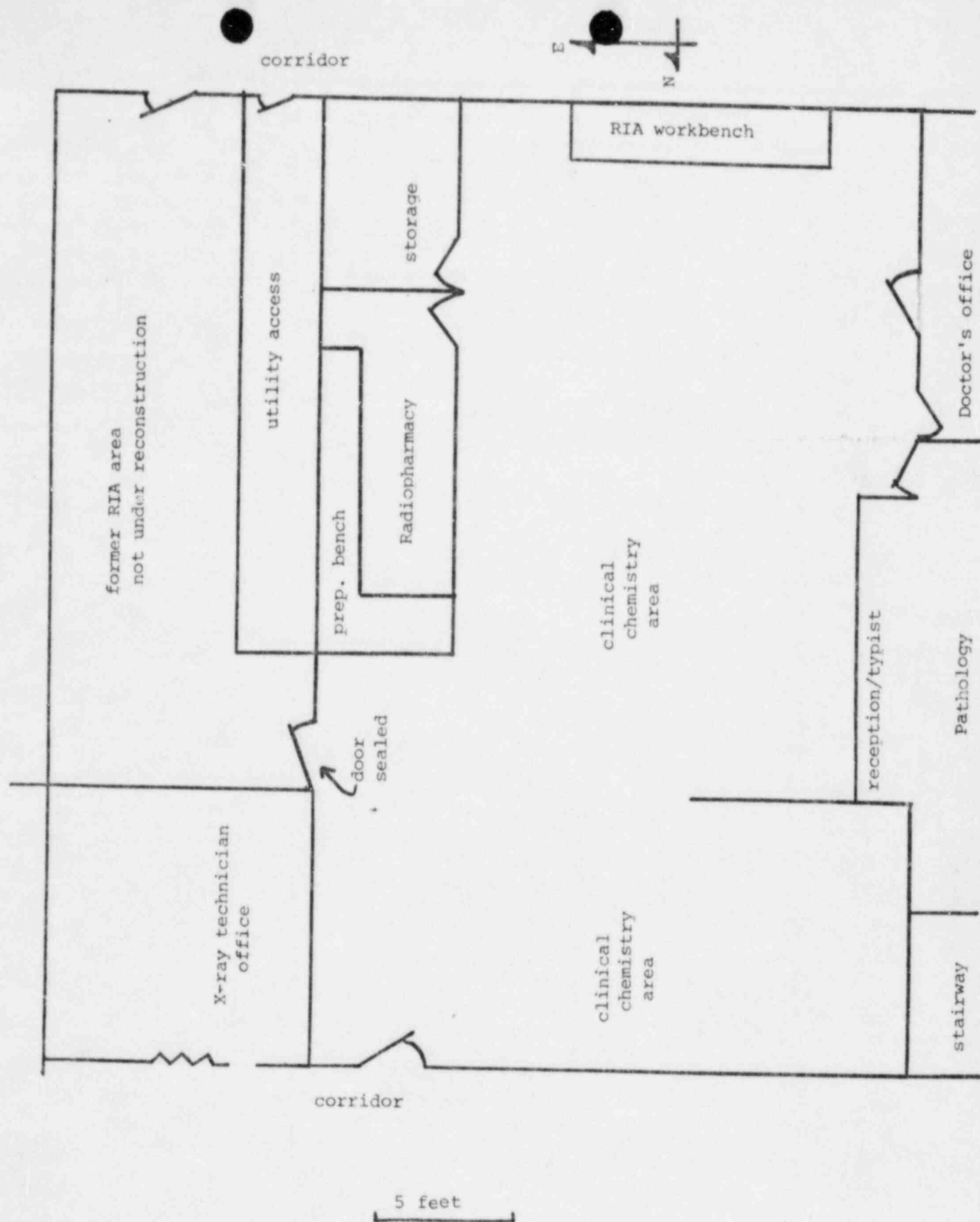
Title: Chemist

Date: June 21, 1982

11876

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Film and Thermoluminescent Dosimetry • X-Ray Calibrations • Radiation Surveys • Health Physics Consultation • Environmental Analyses • Bioassays



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Administration

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DEC 1 1981

U.S. NUCLEAR REG.
COMMISSION
MAIL SECTIONNUCLEAR MEDICINE SERVICE
(115)

November 24, 1981

James J. Smith, M.D. (115)
Director, Nuclear Medicine Service
Veterans Administration Central Office
Department of Medicine and Surgery
Washington, D. C. 20420

Subject: Your letter of October 27, 1981, relative to amendment #19
to NRC license No. 04-01935-03.

Dear Dr. Smith:

The nuclear medicine imaging facility which was moved to another floor in the hospital did not include the Radiopharmacy (Hot Lab). The Radiopharmacy still remains in its original location.

Since the old nuclear medicine facility utilized mainly the Tc-99m radioisotope of a 6 hour half-life, and since the old facility had relatively few nuclear medicine procedures performed within it, then relatively low radioactive contamination levels if any contamination would be expected.

The attached survey record shows that no areas of contamination were found within the old imaging facility.

Thus, we request that the above information be accepted as sufficient evidence to release the old imaging facility for unrestricted use.

R. D. Thompson, M.D.
R. D. THOMPSON, M.D.
Radiation Safety Officer

Attachment

FEE EXEMPT

DEC 18 1981

James J. Smith M.D.
JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

10485

SURVEY OF "FORMER"
NUCLEAR MEDICINE
AREA. NUC. MED IS
NOW LOCATED IN
E-306, 308 & 310.

READINGS IN TURFAN (AVG.)

8/14/82
DEAN

storage 31
corridor 30
elevator 29

Radioimmunoassay Laboratory

24

X-ray room
office

32

23 utility room

24

0.055

0.020

0.019

0.021

closed

0.031

Imaging Laboratory

0.021

nuclear
cardiology

19

reception/typist
Pathology Dept.

20

stairway

FRESNO VAMC

Pathology Dept. office

18

Instrument

INDUSTRIAL CORP.
M/N 3700
S/N VAH 2919



N/A

N/A

N/A

0.061

N/A

N/A

N/A

N/A

N/A



Veterans
Administration

Medical Center

2615 East Clinton Avenue
Fresno, CA 93703

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SEP 16 1981

NUCLEAR MEDICINE SERVICE
(115) 1981 SEP 22 AM 10



August 18, 1981

James J. Smith, M.D. (115)
Director, Nuclear Medicine Service
Veterans Administration Central Office
Department of Medicine and Surgery
Washington, D.C. 20420

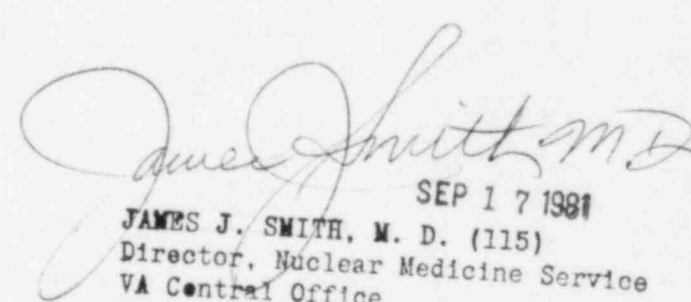
SUBJ: Amendment #19 to NRC License No. 04-01935-03

1. In Amendment #18 to NRC License No. 04-01935-03, we stated in Item 11, Page 1, that in 1981 our Nuclear Medicine facility, excluding the Radiopharmacy (hot lab), would move from the second floor to new quarters on the third floor, Rooms 306, 308, 310 of the Veterans Administration Medical Center, Fresno, California. This move is now complete. A map of the new facility, as well as a photocopy of Item 11, Page 1, is attached to this letter for your information. It is to be noted that the Radiopharmacy remains on the second floor as originally intended.
2. Our Radioactive Waste Storeroom has been moved from the basement, Room C12C to the sixth floor, Room C6U1. The waste material will be secured by a locked door to the storage room. This storage area will be surveyed at least weekly.
3. We request that the changes be included in our license through amendment #19 as follows:
 - a. New third floor location of nuclear medicine facility, Rooms 306, 308, 310.
 - b. New sixth floor location of Radioactive Waste Storeroom, Room C6U1.
4. Form NRC - 313M is also enclosed.


J. J. MASON

Director

FEE EXEMPT

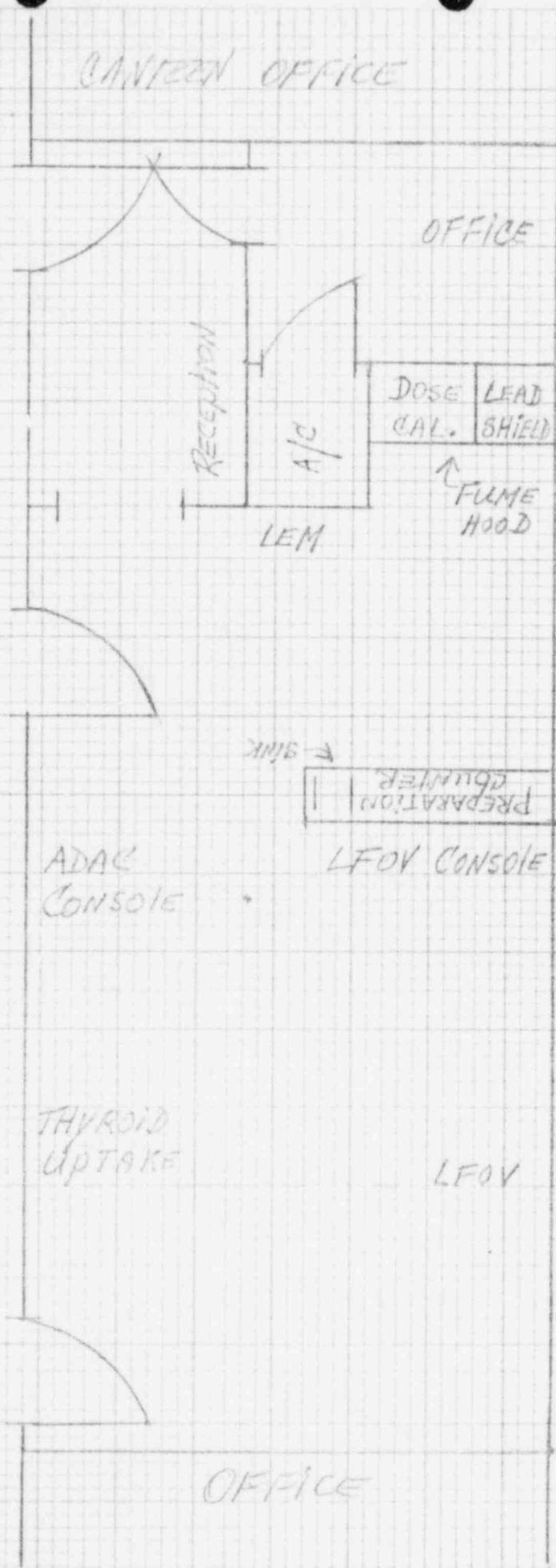

SEP 17 1981
JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

In Reply Refer To: 570/114

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INSPECTION AND ENFORCEMENT

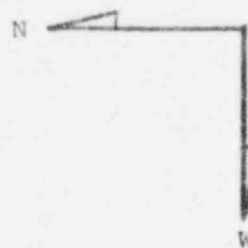
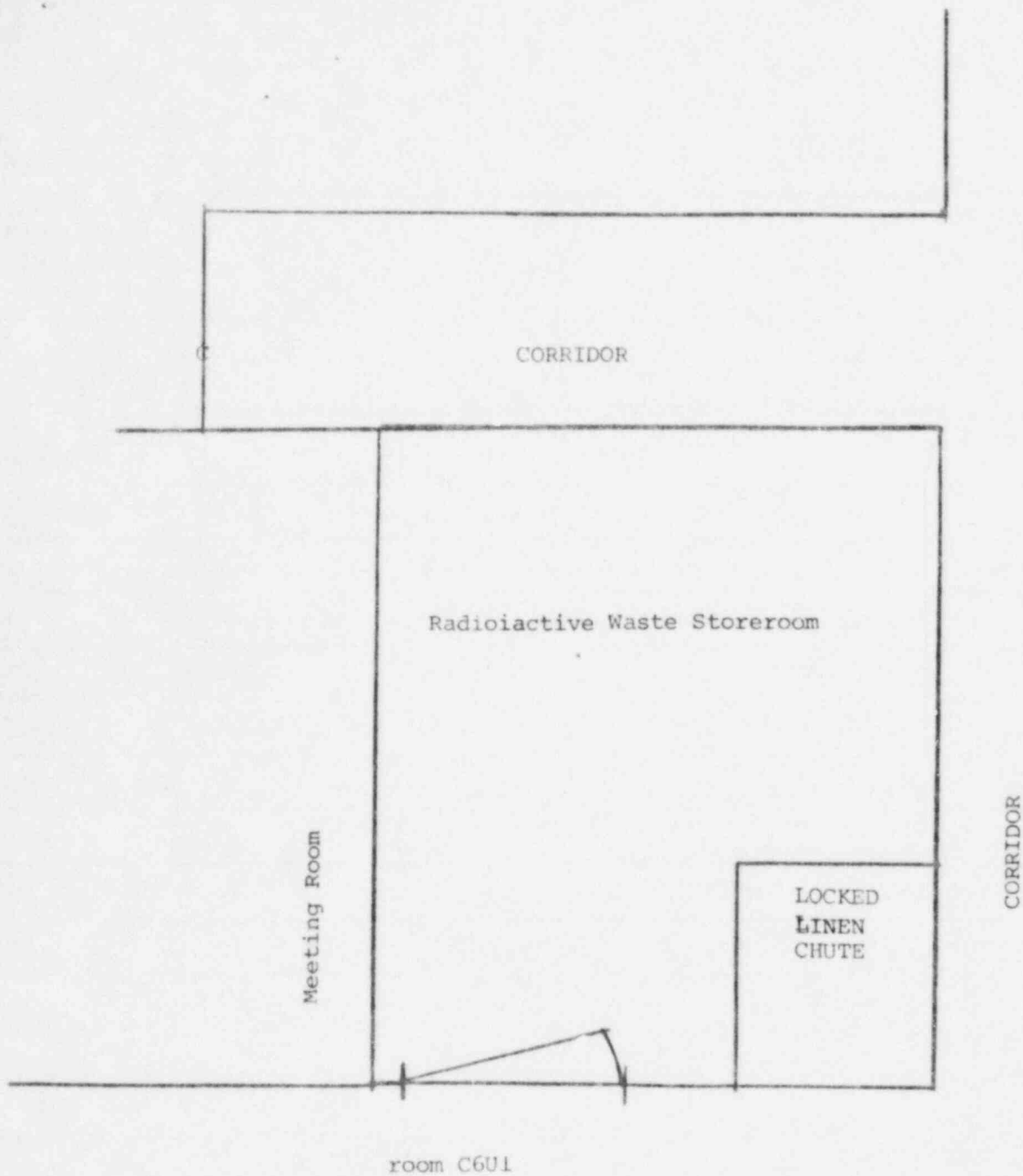
Nuclear Medicine Rooms E306, 308, 310

APPROX. 4' ONE FOOT



OUTSIDE - 2ND FLOOR

TAKEN FROM ENG. DRAWING D-1107



09040

FACILITIES and EQUIPMENT

By-product material are used in the following hospital facilities:

- a. Nuclear Medicine Clinic
- b. Radiopharmacy
- c. Laboratory of Radio immunoassay
- d. Laboratory of Microbiology
- e. Storage of radioactive waste

A. Nuclear Medicine Clinic:

The Nuclear Medicine Clinic is located in the second floor and the diagram of its present facilities is attached on page 3, Item 11.

On December 29, 1980 the remodeling of a 600 square feet area on the 3rd floor has been started to relocate the Nuclear Medicine Clinic. The layout diagram for the new facilities is included in page 4, Item 11. The remodeling job will be finish for March 15th and instruments will be moved to the new facilities on the 3rd week of March.

In the new facility the area indicated as: "Dispensary of Radiopharmaceuticals" consist of a fume hood and a bench of 2 x 2 feet. The fume hood will be used to store the patient unit doses (prepared at the radiopharmacy) during the period of time immediately before administration to the patients. Patient unit doses will be in a shielded syringe placed into a individual lead lined syringe carrier behind the lead brick wall. The lead brick wall consists of interlocking bricks of 2 x 4 x 9 inches.

The front and posterior walls are 36 x 24 inches and the lateral walls are 20 x 24 inches.

Immediately before administering a dose to a patient, prescribed activity is rechecked in the dose calibrator located on the nearby bench.

B. RADIOPHARMACY:

The radiopharmacy is located in the second floor (see layout diagram in page 3, Item 11). As shown in the diagram it has a 10 x 2 feet, L shape stainless steel top bench.

a. Mo 99-Tc 99m generators in use are into their own special shield, behind a lead brick shield.

b. All radiopharmaceuticals and small reference sources are stored in the lead lined refrigerator, located below the bench. In the refrigerator each radiopharmaceutical and each reference source is stored in its individual lead vial shield. The thickness of each individual lead vial shield is a function of the type of decay, the radiation energy and amount of radionuclide in each vial.

c. The weekly produced radioactive waste is stored in the box located in the corner of the bench, behind the lead brick shield.

d. The lead brick wall consist of 2 x 4 x 4 inch interlocking bricks. It measures 60 inch long and 20 inch high.

CS040