Medical and Regional
Office Center

Togus ME 04330

Veterans
Administration

JAN 14 1986

In Reply Refer To: 402/115
License #18-07561-01

U.S. Nuclear Regulatory Commission
Nuclear Materials Safety and
Safeguards Branch
Region I
631 Park Avenue
King of Prussia, PA 19406

Dear Sir:

Enclosed is our formal application for our institution's license to be amended to include the use of Xenon-133 for diagnostic lung ventilation studies. Richard D. Baldwin, M.D., Chief, Nuclear Medicine Service, prepared this document, and may be contacted at FTS 833-5583 should you have any questions.

Sincerely,

for and in the absence of
JOHN D. BUNGER
Center Director

Enclosure

FEE EXEMPT

for Helen MacEachern
and in absence of
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420
1/21/86

NRC

XENON AMENDMENT

NUCLEAR MEDICINE SERVICE (402/115)
VA MEDICAL & REGIONAL OFFICE CENTER
TOGUS, MAINE 04330

NRC LICENSE #18-07561-01

TABLE OF CONTENTS

XENON AMENDMENT

SECTION I

MEMORANDUM FROM SAFETY OFFICER

Veterans Administration

Memorandum

Date: January 10, 1986

From: Safety Officer (138)

Subj: Xenon Amendment (Ref: Your memo dated 1/6/86)

To: Chief, Nuclear Medicine Service (115)

1. The following information is submitted as requested by the referenced memorandum.

2. There are three (3) exhaust stacks from Nuclear Medicine. One of these measures 10" x 10" and exhausts air taken from the hot lab and the dark room. There are separate exhaust ducts from the hot lab hood and scan room #2 which measure 12" x 12" and 8" x 8" respectively. All three exhausts are located side by side at roof level above the clinical laboratory in the southwest corner.

3. The air intake for the air conditioning unit supplying the clinical laboratory is two feet above roof level and located 27 feet from the above mentioned exhaust ducts. Since xenon is much heavier than air and the associated exhaust is at the base of a steep rising wooded hill, there would be no probability of updrafts that could cause the spent gases to enter the air conditioning intake. It should be mentioned also, that the exhaust ducts are angled toward the ground and there is a 12" high parapet above the ducts and around the periphery of the roof that would present a further obstacle to any spent gases. Note that there are no adjacent buildings.

4. This Center's preventive maintenance program includes a quarterly inspection of all exhaust systems in Nuclear Medicine Service and resulting reports are to be forwarded as requested.

5. Should you desire further information, I may be reached at ext. 285 or 366.

Lee C. Calderwood

LEE C. CALDERWOOD

cc:
Chief of Staff (11)

SECTION II

AIR FLOW DATA SHEETS

TABLE V-1

VENTILATION MEASUREMENTS

LOCAL EXHAUST VENTILATION HOODS

VETERANS ADMINISTRATION MEDICAL CENTER

TOGUS, MAINE

JULY - SEPTEMBER, 1985

LOCATION	OPERATION	EXHAUST CFM	CAPTURE VELOCITY AT HOOD FACE (fpm)
Main Laboratory	AA Flame	55	110
	Toxicology Hood	107	10-35
	Coulter Counter	68	180-360
Histology	Xylene Bench	462	30-40
	Dissecting Sink	119	10-20
Bacteriology	TB Hood	167	96
Dental Lab	Flask Casting	368	94
	Oven Vent	469	242
Electron Microscope	Fume Hood	321	50-60 @14"
Engineering	Welding	450	10-20
	Carpentry	552	>100
VOC/REHAB	Carpentry	1962	1500-3000
	Oil Staining	400	10-15
	Welding	110	10
REC/REHAB	Ceramic Shop		
	Leather Staining	250	30
BIOMED	Fume Hood	424	90 @12"

LOCATION	OPERATION	EXHAUST CFM	CAPTURE VELOCITY AT HOOD FACE (fpm)
Nuclear Medicine	Scan Room #2	190	27
	Fume Hood	689	95
Building 200 Room 358	Endoscopy	70	*
Central Services	ETO Sterilizer	43	50
	AMSCO Machine Slots	104	843
	Air Washer Slot	61	42
	Steam Sterilizer Slots		
	(Window Closed)	--	193
	(Window Open)	--	128
	ETO Sterilizer Canopy (Dirty Side)	--	20

* Not a capture hood but should be maintained as a special exhaust system.

TABLE V-2

VENTILATION MEASUREMENTS

DARK ROOMS

VETERANS ADMINISTRATION MEDICAL CENTER

TOGUS, MAINE
JULY - SEPTEMBER, 1985

DEPARTMENT	LOCATION	SUPPLY CFM	EXHAUST CFM	ACH RATE	PRESSURE RELATION
Radiology	Room 138A	90	50	6.6	Positive
	Room 133	100	15	17.1	Positive
	Room 129	340	75	9.4	Positive
Nuclear Medicine	Room 263D	27	73	4.7	Negative
	Room 263C	25	60	4.9	Negative
Dental	Room 110A	ND	into 112	---	---
Medical Media	Color Dark Rm.	--	50	---	Negative
	Dark Room	--	182	---	Negative
Pathology	EM Dark Room	Closed	Return Air	---	Negative

VA DESIGN CRITERIA NOTES

DARK ROOMS -

Air Change Rates - 10 air changes per hour
- negative pressure relative to adjacent areas

Supply Air - 2 air changes of outdoor air per hour supplied to room
- no recirculated air within room units

Exhaust Air - All exhaust air directly exhausted to outdoors

NOTE: ACH = Air Changes per Hour

TABLE V-3

VENTILATION MEASUREMENTS

NUCLEAR MEDICINE

VETERANS ADMINISTRATION MEDICAL CENTER

TOGUS, MAINE

JULY - SEPTEMBER, 1985

ROOM #	LOCATION	SUPPLY CFM	EXHAUST CFM	ACH RATE	PRESSURE RELATION
263	Corridor	100	55	4.4	---
263A	Office	27	30	1.6	ND
263B	Hot Lab	175	919	9.0	Negative*
263C	Dark Room	25	60	4.9	ND
263D	Film Process	27	73	4.7	Negative
263E	Scan Room #1	325	325	10.9	Negative
263F	Scan Room #2	150	190	6.3	Negative
----	Toilet	--	23	--	ND
261	Office	47	57	2.5	ND

ACH = Air Changes per Hour

ND = Not Determined

* NOTE: With fume hood off, total exhaust was approximately 230 CFM and room was negative to corridor.

TABLE V-4

VENTILATION MEASUREMENTS

LABORATORIES

VETERANS ADMINISTRATION MEDICAL CENTER

TOGUS, MAINE

JULY - SEPTEMBER, 1985

ROOM #	LOCATION	SUPPLY CFM	EXHAUST CFM	ACH RATE	PRESSURE RELATION
270	Laboratory	2394	3350	9.1	Negative to 264
270A	Conference	123	341	4.0	ND
270B	Bacteriology	417	520	7.2	Positive to 270
270C	T.B. Mycology	319	346	16.5	Negative to 270
270D	Serology Office	100	83	7.5	Positive to 270
270E	Flam. Storage	---	19	---	Negative to 270
270F	Vestibule	110	--	9.8	---
265	Histology	416	581	21.2	Positive to 264
264	Corridor	ND	ND	ND	Negative to Hospital

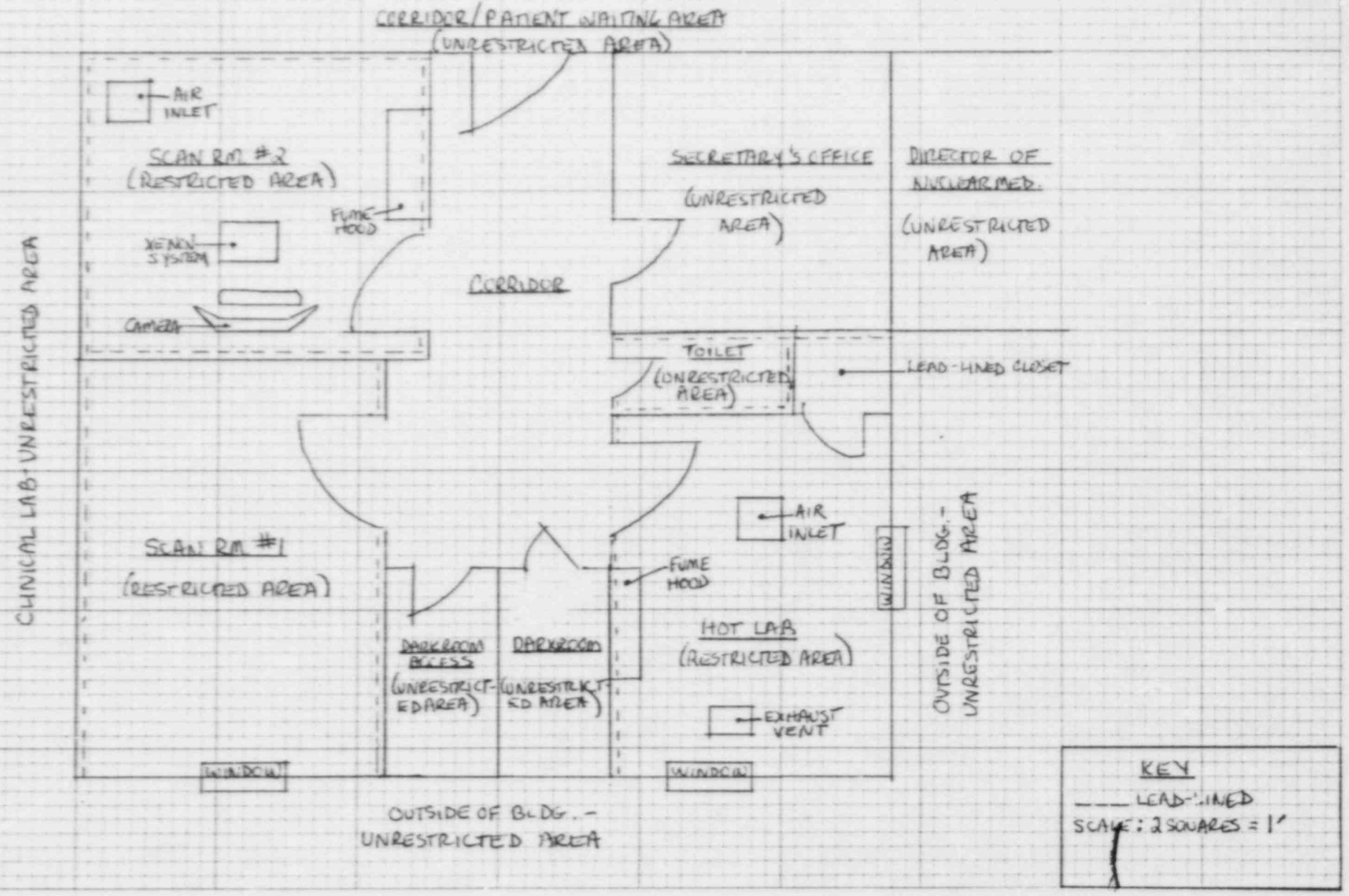
ND = Not Determined

ACH = Air Changes per Hour

SECTION III

FLOOR PLAN OF NUCLEAR MEDICINE SERVICE

UTILIZATION PHASE - XENON SYSTEM PLACEMENT / NUCLEAR MEDICINE SERVICE, VAMHRDC, TOGUS, MAINE 04330

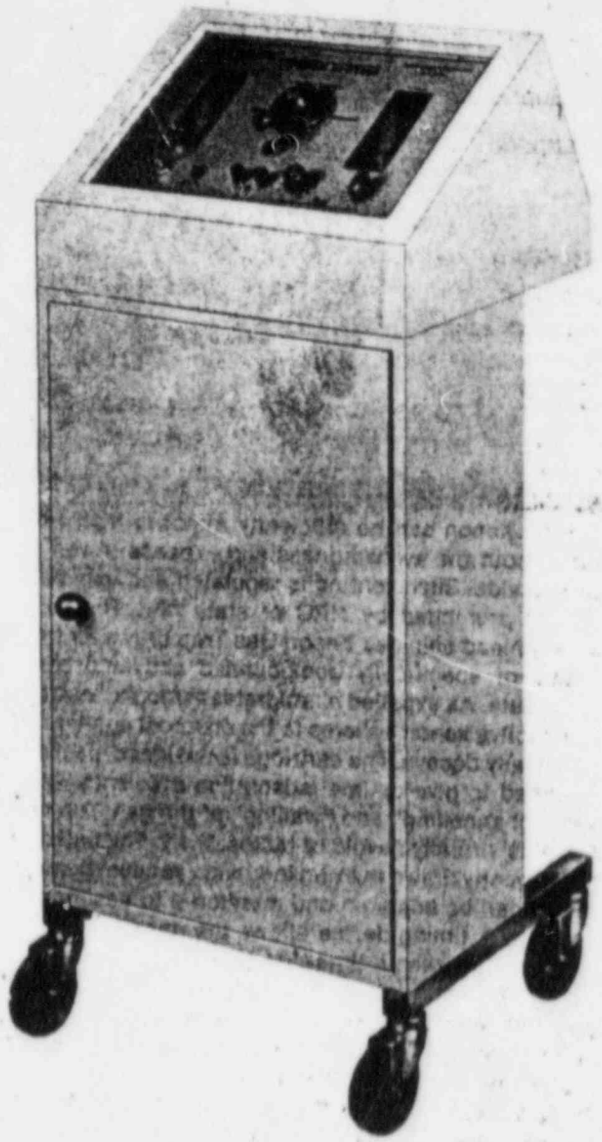


SECTION IV

PULMONEX XENON SYSTEM

PULMONEX XENON SYSTEM

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



SIMPLE, SAFE OPERATION

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

- 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.

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

All controls are conveniently located on an "upfront" control panel. The user can control the system and observe the patient and gamma camera from one position. The control panel is clarly marked for each mode in the procedure. 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 automatically shuts down the system to complete the study after patient and system washout. The system may be restarted by turning the timer on.

The PULMONEX SYSTEM

The Pulmonex Xenon System effectively integrates manual and electronic controls into a simple 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 rheostat with variable dial operates a circulator blower motor to provide gentle positive system pressure. This specially-designed master valve and wide diameter, short circuit airways, provide resisttance-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 shut-down control and two variable pressure controls to accommodate your patients breathing pattern and to assure complate system washout into gas trap.

All internal systems are completely shielded for patient and operator safety. A bacteriostatic filter used at the mouthpiece prevents 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 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,..... **$2750.00**

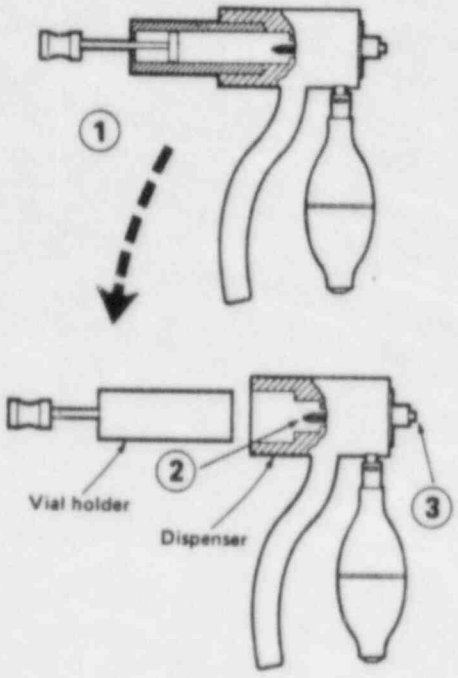
REPLACEMENT ITEMS

127-319 Replacement Charcoal Cartridge....**$340.00**
130-550 Disposable Mouthpiece..... **1.95 ea.**
130-700 Disposable Bacteria Filter..... **$3.50 ea.**
129-701 Moisture Absorber (Drierite)..... **8.00 lb.**
130-019 Soda Lime, CO_2 Absorber..... **5.50 lb.**
067-130 220V Converter.....**$150.00**

SECTION V

NEN CALIDOSE DISPENSER

Operation Instructions for **NRP-186 CALIDOSE™ DISPENSER** for use with **NRP-127 XENON Xe 133 GAS**



Loading

1 Separate shielded vial holder from dispenser.

2 Check Huber point needles inside the dispenser body to insure that they are not blocked (if necessary, clean by pushing a fine wire through needles).

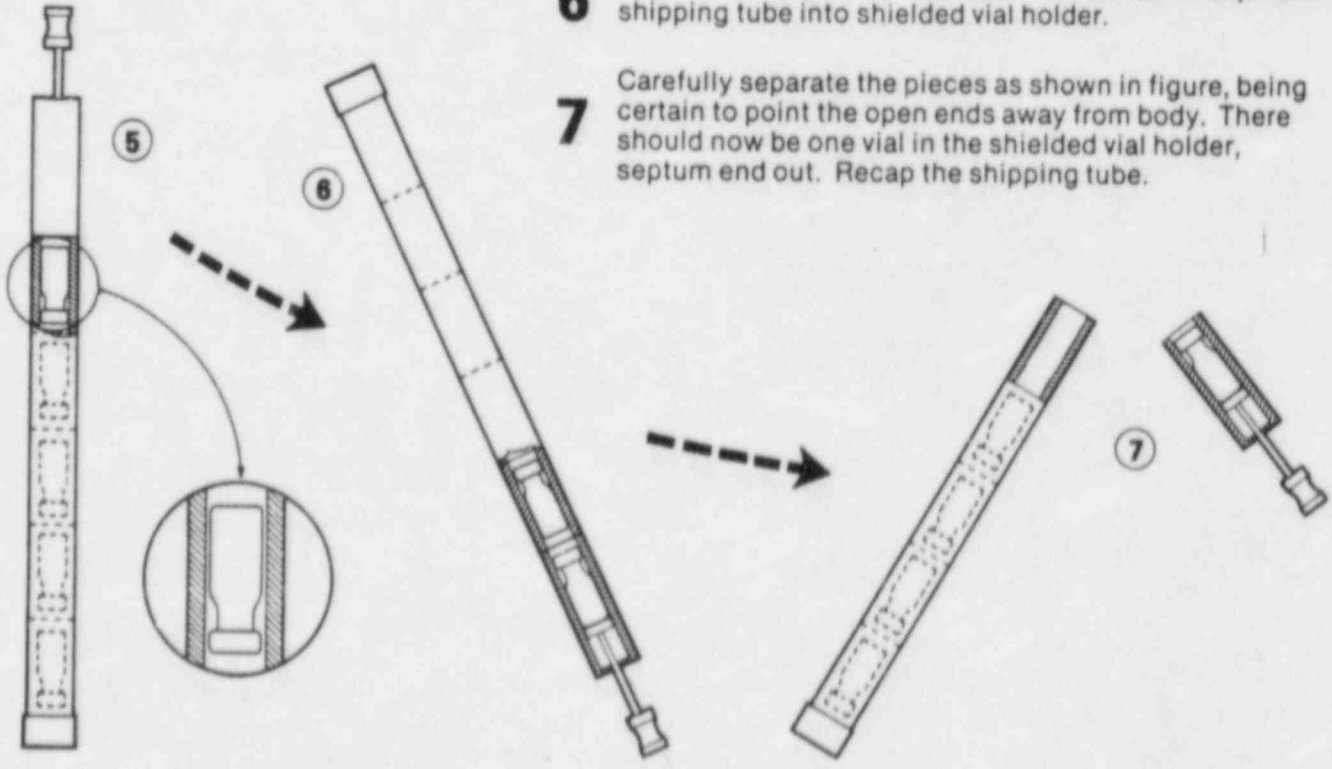
3 Attach a hypodermic needle (or other connector) securely to Luer Lock fitting on front end of dispenser.

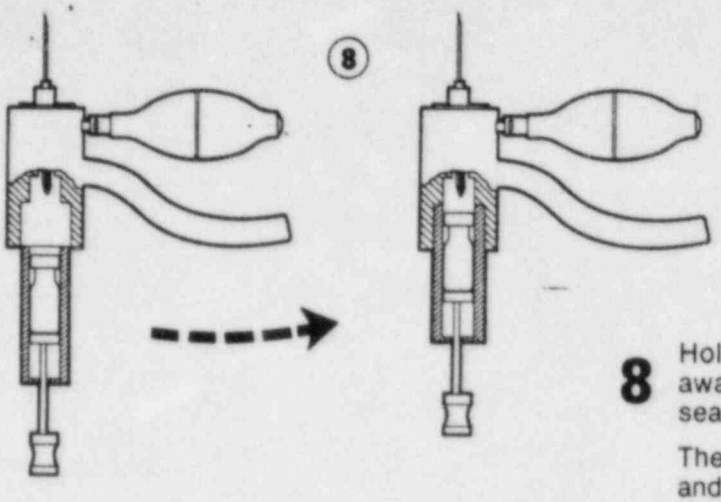
4 Remove the yellow cap of the ^{133}Xe lead shipping tube, being careful to point opened tube away from body.

5 Place the open end of the shielded vial holder tightly against the open end of the shipping tube.

6 Simultaneously invert both to allow one vial to slip from shipping tube into shielded vial holder.

7 Carefully separate the pieces as shown in figure, being certain to point the open ends away from body. There should now be one vial in the shielded vial holder, septum end out. Recap the shipping tube.

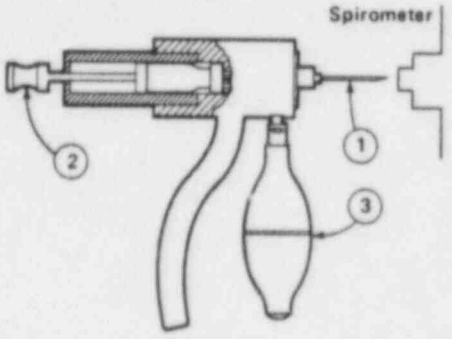




8 Holding the shielded vial holder upright (and pointed away from body), insert it into the dispenser until seated. DO NOT PUSH PLUNGER IN AT THIS TIME.

The loaded CALIDOSE Dispenser is now ready for use and can be put aside until needed. Note that appropriate radiation protection precautions must be taken since radiation can escape from the front of the unit.

Using



1 Affix the CALIDOSE Dispenser to a spirometer or related breathing apparatus.

2 Puncture septum of loaded vial by pushing plunger into dispenser.

3 Immediately squeeze the rubber bulb, and then release.

4 Detach CALIDOSE assembly from breathing apparatus.

Storing

Remove vial holder from dispenser. The previously used vial will not contain enough residual ^{133}Xe to be harmful, and may be removed by hand for disposal in the radioactive waste. Replace vial holder in dispenser for easy storage.

Statement

This CALIDOSE™ Dispenser is a device protected by U.S. Patent 3,848,773 and other patents are pending. It is to be used solely for the purposes of dispensing New England Nuclear's Xenon 133 gas Catalog Number NRP-127 as defined in New England Nuclear's NDA No. 17-284 submission. This device remains the sole property of New England Nuclear, and must be returned to New England Nuclear, Atomlight Place, North Billerica, Mass. 01862, should it cease to be used as described.

SECTION VI

NEN XENON PACKAGE INSERT

NEN New England Nuclear

XENON Xe 133 GAS

Catalog Number NRP-127

DESCRIPTION

Xenon Xe 133 for diagnostic use is available as 5% gas in carbon dioxide diluent 95%.

ACTIONS

Xenon Xe 133 is a readily diffusible gas which is neither utilized nor produced by the body. It passes through cell membranes and freely exchanges between blood and tissue. It tends to concentrate more in body fat than in blood, plasma, water or protein solutions. In the concentrations used for diagnostic purposes it is physiologically inactive. Inhaled Xenon Xe 133 gas will enter the alveolar wall and enter the pulmonary venous circulation via the capillaries. Most of the Xenon Xe 133 that enters the circulation from a single breath is returned to the lungs and exhaled after a single pass through the peripheral circulation.

INDICATIONS

Inhalation of Xenon Xe 133 gas has proved valuable for the evaluation of pulmonary function and for imaging the lungs. It may also be applied to assessment of cerebral flow.

CONTRAINDICATIONS

To date, no known contraindications to the use of Xenon Xe 133 gas have been reported.

WARNINGS

This radiopharmaceutical should not be administered to pregnant or lactating women unless the benefits to be gained outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of the menses.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

PRECAUTIONS

As in the use of any other radioactive material care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers. Expired Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate governmental agency regulations.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. Such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic. Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

ADVERSE REACTIONS

To date, no adverse reactions based on the use of Xenon Xe 133 gas have been reported.

DOSAGE AND ADMINISTRATION

Xenon Xe 133 gas is administered by inhalation from closed respirator systems or spirometers.

The suggested activity range employed for inhalation by the average adult patient (70kg) is:

Pulmonary function including imaging: 2-30mCi in 3 liters of air.

Cerebral blood flow: 10-30mCi in 3 liters of air.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

PHYSICAL CHARACTERISTICS

Xenon Xe 133 decays by beta and gamma emissions with a physical half-life of 5.27 days[1]. Photons that are useful for imaging studies are listed in Table I.

Table I
Principal Radiation Emission Data Xenon Xe 133

Radiation	Mean % per Disintegration	Mean Energy (keV)
Beta-2	99.3	100.6
Gamma-2	34.99	81.0
K int. con. electrons, -2	47.24	45.0
L int. con. electrons, -2	7.87	75.7
M int. con. electrons, -2	9.84	80.0
K X-rays	34.70	30.8
K X-rays	7.67	35.2

(1) Dillman, L.T., Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation, Part 2, Supplement No. 4, MIRD pamphlet No. 6, J. Nucl. Med., p. 28, 1970.

The specific gamma ray constant for Xenon Xe 133 is 0.44R/mCi-hr. at 1cm. The half value layer is 1mm of Pb. To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals before and after the date of calibration are shown in Table II.

Table II
Xenon Xe 133 Physical Decay Chart
(Half-life 5.27 days)

Day	Fraction Remaining	Day	Fraction Remaining
-5	1.930	8	.349
-4	1.693	9	.302
-3	1.483	10	.268
-2	1.300	11	.235
-1	1.140	12	.206
0*	1.000	13	.181
1	.877	14	.159
2	.769	15	.139
3	.674	16	.122
4	.591	17	.107
5	.518	18	.094
6	.454	19	.082
7	.398	20	.072

*Calibration Day

RADIATION DOSIMETRY

The estimated absorbed radiation doses[2] to an average patient (70kg) for pulmonary perfusion and cerebral blood flow studies from a maximum dose of 30 millicuries of Xenon Xe 133 in 3 liters of air are shown in Table III.

Table III
Radiation Doses

	Effective Half-time	Lungs*	Brain	Whole Body
		rads/30mCi		
Pulmonary Perfusion	2 min.	0.25	0.0014	0.0027
Cerebral Blood Flow	5 min.	0.63	0.0035	0.0068

*99% of activity is in lungs

(2) Method of Calculation: A Schema for Absorbed-Dose Calculation for Biologically Distributed Radionuclides, Supplement No. 1, MIRD pamphlet No. 1, J. Nucl. Med., p. 7, 1968.

HOW SUPPLIED

The Xenon Xe 133 gas is supplied as part of the CALIDOSE™ system, consisting of 2ml unit dose vials and the CALIDOSE dispenser* for shielded dispensing.

Normally vials containing either 10 or 20mCi/vial, packed up to 5 vials per shield tube, are supplied. Vial sets containing up to 100mCi/vial are available.

*Patent Pending

NEN New England Nuclear
Radiopharmaceutical Division
Atomlight Place, North Billerica, Mass. 01862

SECTION VII

ITEMIZED AMENDMENT

ITEMIZED AMENDMENT, XENON-133

1. COMPLETE AND CORRECT NAME AND ADDRESS:

VA Medical & Regional Office Center
Togus, Maine 04330
Attn. Richard D. Baldwin, M.D.
Chief, Nuclear Medicine Service (402/115)

2. CURRENT RADIOACTIVE MATERIALS LICENSE NUMBER: 18-07561-01

3. RADIOACTIVE MATERIAL: Xenon-133

4. TYPE OF STUDY: Pulmonary Ventilation Study

5. POSSESSION LIMIT: 300 mCi

6. DOSAGE EMPLOYED: 10 mCi per patient. Higher doses will be used only when professional medical judgment indicates it to be necessary.

7. PATIENT LOAD: (Estimate) 7 patients per week, 364 patients per year

8. SOURCE OF RADIOPHARMACEUTICAL:

Dupont/New England Nuclear, Inc.
331 Treble Cove Road
N. Billerica, MA 01862
(See package insert, Sectio VI)

9. IMAGING EQUIPMENT: Technicare Model 420/550 gamma camera with on-board computer

10. SPECIAL EQUIPMENT:

a. Delivery System - Dupont/New England Nuclear Calidose Dispenser system (see Section V)

b. Lung Function Unit - Atomic Products Corporation, P.O. Box 1157, Center Moriches, NY 11934, Catalog Number 130-500, Pulmonex Xenon System (see Section IV)

c. Disposal System - Xenon Gas Trap (integral part of Pulmonex system) (see attached product literature, Section IV)

11. DOSE CALIBRATION: All doses for patient use will be checked immediately prior to use with a Capintec Model CRC-30 Radioisotope Calibrator

12. PERSONNEL SAFETY: All personnel working in the department will use both whole body film badges and TLD finger badges

13. SCALE DRAWING: See Section III.

14. DESCRIPTION OF STORAGE AREA:

The Xenon-133 Gas will be stored in its lead shipping container (1/8" lead) in an enclosed, lead-lined box (1/2" lead) which is behind a 2" lead barrier.

There are two components to the ventilation system: 1) an exhaust vent which is operated continuously with an exhaust flow of 230 cfm (see Section II); and 2) a fume hood for use in emergencies which has an exhaust rate of 689 cfm (see Section II).

The Engineering Service will check the flow rate of the exhaust fan quarterly (see Section I). If necessary, the filter will be changed and the exhaust rate re-checked. A record of this will be kept in the equipment maintenance log book.

The volume of the hot lab is approximately 1280 cu. ft. The total air flow (including fume hood) equals 919 cfm.

The time for one air exchange is 1.4 minutes. The time for 10 exchanges is 14 minutes. The maximum concentration of Xenon-133 over 40 hours in 7 consecutive days for this restricted area has been calculated on the following basis:

a. Maximum amount of Xenon-133 activity per week is 300 mCi (Xenon trap will be stored in this area when not in use).

b. Estimated escape fraction (maximum Xenon-133 lost due to leakage or inadvertent release) is 0.25.

c. Air flow volume will be 230 cfm. This results in a concentration of 4.8×10^{-6} uCi per ml per 40-hour week.

$$V = 230 ft^3/min \times 60 min/hr \times 40 hr/wk \times 2.832 \times 10^4 ml/ft^3 = 1.56 \times 10^{10} ml/wk$$

$$A = 300 \text{ mCi}$$

$$F = 0.25$$

$$C = \frac{300 \times 10^3 uCi \times 0.25}{1.56 \times 10^{10} ml/wk} = 0.48 \times 10^{-5} \text{ uCi/ml}$$

This verifies that the MPC of 1×10^{-5} uCi/ml as stated in Section 20.103 of CFR Part 20 and Schedule B Table 1 of Part 20 will not be exceeded.

In the event of an accidental release of Xenon-133 in this area, the following procedure will be implemented: The switch of the fume hood will be turned on, and the window fully opened. All personnel will leave the room and close the door. The room will remain unoccupied for 30 minutes. Upon re-entry, the room will be surveyed with a low-level survey meter to insure the radiation levels have returned to normal for the area. Upon verification of the above, the fume hood will be turned off.

The 30-minute period will insure changes of the room air based upon the following calculations:

Air flow velocity = 919 cfm

Room volume = 1280 cu.ft.

$$\frac{\text{Room volume}}{\text{Exhaust volume/min.}} = 1.4 \text{ minutes}$$

20 exchanges would require 28 minutes.

The air which is exhausted from this room is released directly into an unrestricted area located on the roof of the hospital. This release point is isolated from all air intakes in adjacent buildings by distances exceeding 50 feet. All restricted areas are in common with this release point, and the calculations for the unrestricted area are presented at the end of the utilization phase discussion.

15. DESCRIPTION OF PROCEDURE:

The Xenon-133 Gas will be used in the following manner: The dose will be measured in our dose calibrator. The patient will be instructed on the details of the procedure with special emphasis on the areas where his cooperation is needed. Just prior to the study, one or more practice runs will be done before the Xenon-133 gas is used. The unit dose vial will be loaded into the shielded Calidose Dispenser furnished by Dupont/New England Nuclear. It will then be taken to the imaging area where the lung ventilation procedure will be done. The Dispenser will be connected to the Atomic Products Corporation Lung Function Unit. The Xenon-133 gas will be administered to the patient via this unit. Nose clamps will be used to prevent the patient from exhaling the Xenon-133 into the room. The lung ventilation procedure will be composed of the three standard phases of breath hold, equilibrium, and washout. (These phases are automatically accomplished as the technician operates the remote control switch of the unit.) Upon completion of the study, the used Xeon-133 will be drawn directly into the Atomic Products Corporation Xenon Gas Trap.

16. DESCRIPTION OF IMAGING ROOM (UTILIZATION AREA):

All Xenon-133 lung imaging will be performed in Imaging Room #2, as shown in Section III and described in our original license submission. Air will enter this room through the door and the ceiling vent. The air will leave the room via a ceiling vent which has a measured air flow of 190 cfm. This room has a slight negative pressure at all times. The maximum concentration of Xenon-133 in this restricted area is calculated below:

a. Maximum amount of Xenon-133 per week = 100 mCi. Estimate based on 100 mCi per week resulting from patient use.

b. Estimated Escape Fraction (maximum Xenon-133 activity lost due to leakage and inadvertent release) is 0.25.

c. Air flow volume will be 190ft^3/min

Therefore, using the preceding values and appropriate conversion factors, C can be calculated.

$$C = \frac{A}{V} \times F = \frac{100\ mCi\ (1 \times 10^3)}{400\ ft^3/min\ (7.797 \times 10^7)} \times 0.25 = 0.194 \times 10^{-5}\ uCi/ml/40\text{-hr.wk.}$$

This verifies that the MPC of 1×10^{-5} uCi/ml as stated in Section 20.103 of CFR Part 20 and Schedule B Table 1 of Part 20 will not be exceeded.

The maximum concentration of Xenon-133 for the Unrestricted Area, the roof exhausts, is calculated below:

a. Maximum amount of Xenon-133 released per year is based upon 300 mCi per week times the Escape Fraction of 0.25:

300 mCi/wk x 0.25 Escape Fraction x 52 wks/yr = 3900 mCi

b. Total air flow volume from all areas equal 1020 ft^3/min. These are added together because they vent simultaneously and exhaust via adjacent roof outlets. Therefore, using the preceding values and appropriate conversion factors, C can be calculated.

$$C = \frac{A}{V} = \frac{3900\ mCi\ (1 \times 10^3)}{2400\ ft^3/min\ (1.484 \times 10^{10}\ ml/yr)} = 2.58 \times 10^{-7}\ uCi/ml\ avg/yr$$

This verifies that the MPC of 3×10^{-7} uCi/ml as stated in Section 20.106 of CFR Part 20 and Schedule B Table 2 of Part 20 will not be exceeded, and that Section 20.1(c) of 10 CFR Part 20 is being complied with.

In the event that there is an accidental release of Xenon-133 in Imaging Room #2, the following emergency procedure will be implemented: The patient will be removed from the room and the door will be closed. All personnel will leave Imaging Room #2 for 15 minutes. Upon re-entry, this room will be surveyed to insure that radiation levels have returned to normal for this area.

The 15 minutes will ensure eleven changes of air in both rooms, based upon the following calculation:

Total air flow volume = 1020 ft^3/min
Total volume of room = 1320 ft^3
Therefore: $\frac{Volume}{Air\ flow}$ = Turnover Time = $\frac{1320}{1020}$ = 1.29 min.

Eleven changes of the air in these rooms would require fifteen minutes.

17. THE DISPOSAL PHASE:

The disposal of Xenon-133 Gas will be done by trapping the Xenon-133 gas in an Atomic Products Corporation Xenon Gas Trap (an integral part of the Pulmonex Xenon System). The potential leakage of Xenon-133 from this unit, as well as other sources of leakage, are included in the Escape Fraction figure. To insure that the trap is working efficiently, we will monitor the exhausted air from the trap using the following procedure: Immediately after the last Xenon-133 lung ventilation procedure each week, a 5-liter polyethylene bag will be placed over the exhaust port of the Xenon trap, and the unit will be operated until the bag is full. The bag will be sealed and placed in front of the gamma camera and counted for one minute at the appropriate settings. The counts per minute (CPM) will be recorded in the equipment maintenance log and compared with previous readings. A replacement cartridge will be installed whenever there is a significant increase in the weekly CPM. The saturated cartridge will be placed in the hot lab in a radiation waste barrel with other radioactive waste. This will be stored for 60 days (10 half-lives) and disposed of with the non-radioactive waste.

18. EQUIPMENT OPERATION AND MONITORING FOR LEAKAGE:

a. The Calidose Dispenser Delivery System will be checked prior to use to insure proper operation. The manufacturer's operating instructions will be followed.

b. The Lung Function Unit will be checked during the practice runs prior to the administration of the Xenon-133 gas. The manufacturer's operating instructions will be followed and the carbon dioxide absorber will be replenished as needed.

c. The Xenon Trap will be checked prior to each ventilation procedure to insure that it is securely connected to the Lung Function Unit. Xenon leakage from the exhaust port will be monitored as previously described. The manufacturer's operating instructions will be followed and the desiccant in the water trap will be checked daily and replenished as needed.

d. All exhaust vents will be checked 4 times a year to confirm their continued efficiency. In addition, they will be checked whenever structural changes are made which would affect their efficiency. Records verifying these procedures will be maintained.