ATTACHMENT # 18

ST. ELIZABETH HOSPITAL
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DIAGNOSTIC RADIOLOGY
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Director
Radioisotope Licensing Branch
Division of Fuel Cycle & Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sirs:

Please amend our NRC License, Number 34-01131-0 to include Xenon 133 as a gas which will be used to perform pulmonary ventilation studies. We request a possession limit of 800 mCi of Xenon 133 gas. A maximum of 30 patient studies per week (1560 per year) will be performed using an average dose of 10 mCi per procedure. Higher doses will be used only when professional medical judgement indicates it to be necessary.

All doses for patient use will be checked prior to administration with either a CRC 10 M or CRC 4 dose calibrator. The Dose Calibrators are calibrated daily with the appropriate long-lived sources (New England Nuclear, NES-360, set of 3 vial "E" sources-Co^{57}, Co^{60}, Cs^{137}) and appropriate records are maintained. All personnel working in the department are subject to personnel surveys utilizing whole body film badges and all personnel handling radioactive materials wear TLD ring badges.

The radiological safety equipment and procedures are the same as those applied for in our original license submission. However, an additional room monitor has been placed in the hot lab, Victoreen Model Number 808-D. Procedures described in this submission will be strictly adhered to as are those procedures already in force.

The radiopharmaceutical will be supplied by New England Nuclear Corp., Atomlight Place, North Bellerica, Mass., 01862. Attachment #2 is a package insert describing the Xenon 133 gas in unit dose vials (catalog number NRP-127). This product has NDA status with the Food and Drug Administration. The special equipment to be used in conjunction with our Searle L.F.O.V. Camera is listed below, and the manufacturer's literature is attached.

1. Calidose Delivery System: New England Nuclear Corporation. Catalog Number NRP-186 refer to Attachment #2.
2. Automated Ventilation Module, Omnimedical, Inc. refer to Attachment #3.
3. Xenon Gas Trap: Omnimedical Xenon Gas Trap, refer to Attachment #4.
4. Kewanee Industry's lead lined storage unit.

Attachment # 5A, 5B, 5C are scale drawings of our facility.

The Xe^{133} gas will be stored in a lead lined drawer contained in the lead Module in the hot lab. This module has a lead casing of a minimum of 1" of lead surrounding the contents. Additionally, storage will be maintained in the 1/8" thick shipping containers provided by New England Nuclear. This unit is set in below the fume hood which provides immediate ventilation to this module. The flow is maintained at 1000 cu ft. per min. when the fan is on low speed and 1500 cu ft. per min. in the high speed position. A 3 button circuit is provided next to and immediately under this hood. The fan is always in the 1000 cu ft. per minute operation. If this system fails and Xenon gas escapes, an area monitor, located on the opposite wall will actuate an audible alarm.

The exhaust hood opening is 2 sq. ft. The total volume of this room is 440 cu. ft. (5' x 11' x 8'). With the door closed, the room is free of air circulation from the outside. All air leaving the room is through the fume hood which also keeps the room at a continuous negative pressure. The maximum concentration of Xenon 133 over forty hours in seven consecutive days for this Restricted Area has been calculated on the following basis:

A. Max. amount of Xe^{133} per week is 800 mCi.
B. Estimated escape fraction is 20% (maximum Xenon 133 activity lost due to leakage and inadvertent release).
C. Air flow volume will be 200 ft.^{3}/min. (1000 ft./min) x 2 sq. ft.

Therefore, using the above data and appropriate conversion factors, C can be calculated:

$$C = \frac{A}{V} \times F = \frac{800{,}000 \text{ uCi} \times 25\%}{2000 \text{ ft.}^3/\text{min.}\ (6.797 \times 10^7)} =$$
$$1.47 \times 10^{-6} \text{ uCi/Ml per 40 hr. wk.}$$

This verifies that M.P.C. of 1×10^{-5} uCi/ml as stated in Sec. 20.103-10 CFR. Part 20 and Schedule B Table 1 of Part 20 shall not be exceeded.

In the event of accidental release of the Xenon-133 in this area, the following procedure will be implemented: The selector switch of the hood will be positioned to the 1500 ft./min. flow velocity. All personnel will leave the room and close the door. The room will remain unoccupied for six 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 selector switch will be returned to 1000 ft./min.

Air flow velocity	=	1500 ft./min.
Area of hood vent	=	2 sq. ft.
Total air volume	=	3000 cu. ft./min.
Volume of room	=	440 cu. ft.

Therefore:

$$\frac{\text{Room volume}}{\text{Air volume/min}} = \text{turn over time} = \frac{440 \text{ cu. ft.}}{3000 \text{ cu. ft./min.}} = 0.15 \text{ mi}$$

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 and adjacent buildings by distances exceeding 50 ft. 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.

All Xenon-133 lung function ventilation procedures will be performed in the L.F.O.V. imaging room (see Attachment 5B areas 3 and 4). Air enters room through two ventilators in the ceiling. The air leaves the room via a 0.7 square foot ceiling vent with a measured air flow velocity of 240 cu. ft./min. The door to the hot lab will be maintained in the open position with the fume hood fan in the 1,000 cu. ft./min. position. Allowing for additional ventilation during the procedure, all other doors will be maintained

in the closed position. The total volume of the imaging room plus hot lab (areas 1, 3, and 4) are 3112 cu. ft. (Attachment 5B). All other air inlets and outlets remain closed during Xe-133 ventilation procedures. The maximum concentration over 40 hours in seven consecutive days for this restricted area is calculated to be:

A. Maximum amount of Xe-133 per week 300 mCi. (Estimate is based on 300 mCi per week resulting from patient use.)
B. Estimated escape fraction is 0.20. (Maximum Xe-133 activity lost due to leakage and inadvertent release).
C. Air flow volume will be 168 cu. ft. (240 cu.ft./min x 0.7 sq.ft.) plus 2000 cu. ft./min (1000 ft./min. x 2 ft.^{2}) Total air flow volume 2168 cu.ft.

Therefore, using the preceeding values and appropriate conversion factors "C" can be calculated:

$$C = \frac{A}{V} \times F$$

$$C = \frac{300,000 \text{ uCi} \times 20\%}{2168 \text{ cu.ft./min } (6.797 \times 10^7)}$$

$$C = 4.07 \times 10^{-7} \text{ uCi/ml}$$

Which is below the N.R.C.-M.P.C. of 1×10^{-5} uCi/ml. As stated in Sec. 20.103 10 CFR Part 20 and Schedule B Table I of Part 20.

In the event that there is an inadvertent release of Xenon-133, the imaging room (area 3 and 4 Attachment 5B), the following emergency procedure will be implemented: The patient will be removed from the room, the fume hood fan selector switch in the hot lab will be set to the 1500 ft./min. position. The door to the hot lab will be left open, and all personnel will leave the imaging room (area 3 and 4 Attachment 5B) and the outer door will be closed. Both the hot lab and imaging room remain unoccupied for 15 minutes. Upon re-entry, both rooms will be surveyed to insure the radiation levels have returned to normal. Upon verification of the above, the selector switch for the fume hood will be returned to 1000 ft./min. A volume of air equal to 15 times the capacity of both imaging room and the hot lab will be exchanged during this 15 minutes as shown in the calculation below.

A. Total volume of 3 rooms 3112 cu. ft.
(5' x 11' x 8') + (15' x 12' x 8') + (7' x 12' x 8')
B. Total air flow volume of the 3 rooms cu. ft./min.
(240 cu.ft./min. x 0.7 sq. ft.) + (1500 cu. ft./min x 2 ft.)
C. Time is 15 minutes

Therefore:

$$\frac{3168}{3112} \times 15 = 15 \text{ minutes}$$

All the exhausted air from both the imaging room and the hot lab are released to an unrestricted area on the roof of the hospital which is isolated by at least 50 ft. from any intakes or buildings. The maximum concentration of Xe-133 averaged over a period of one year is calculated as follows:

Maximum amount of Xe-133, unrestricted area, the roof exhaust, is:

A. Maximum amount of Xenon-133 released per year based on 800 mCi per week times the escape fraction of 20%.

800 mCi/wk x 20% x 52 wks/yr = 8320 mCi

B. Total air flow from all areas equals 3168 cu. ft. /min. (These are added together because they are dumping into parallel exhaust ducts which lead to the roof).

Therefore:

$$C = \frac{A}{V} = \frac{8,320,000 \text{ uCi}}{3168 \text{ cu.ft./min.} \times 1.484 \times 10^{10} \text{ ml/yr}}$$

$$C = 1.77 \times 10^{-7} \text{ uCi/ml average/year}$$

This verifies that the M.P.C. of 3×10^{-7} uCi/ml as stated in Section 20.106 10 CFR Part 20 and Schedule B Table 2 of Part 20 will not be exceeded. Also Section 20.1 (C) of 10 CFR Part 20 is therefore in compliance.

The Xenon 133 gas will be used in the following manner after confirming the dose by measurement in our Dose Calibrator. The patient will be instructed on the details of the procedure and will be told why his cooperation is needed. Just prior to the study with the Xenon 133 gas, one or more practice runs will be accomplished. The unit dose vial will be loaded into the shielded NEN Calidose Dispenser in the Hot Lab. It will then be taken to the imaging area where the lung ventilation procedure will be performed. The Dispenser will be connected to the Automated Ventilation Module. The Xenon 133 gas will be administered to the patient via this unit. Nose clamps will routinely be used to prevent the patient from exhaling the Xenon 133 into the room. The lung ventilation procedure will routinely 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 Xenon 133 gas will be drawn directly into the Omnimedical gas trap.

The potential leakage (Escape Fraction) of Xenon 133 gas is assumed at 20%. To insure that the trap is working efficiently, the following procedures will be used. Immediately after the last scheduled Xenon 133 lung ventilation study of the week, a 5 liter polyethylene bag will be placed over the exhaust port of the Xenon Trap. 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 on the appropriate settings. The Counts Per Minute (CPM) will be recorded in a record book 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 radiation waste barrel, in the Hot Lab, with other radioactive waste, and disposed after background levels are obtained in the approved manner set forth in our original license submission.

In order to insure that a minimum of Xenon 133 leakage occurs and that equipment works correctly, the following procedures will be followed:

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 Automated Ventilation Module will be checked at the beginning of each week by filling it with oxygen and checking for leakage. Its operation will be checked during the practice runs prior to 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 Automated Ventilation Module 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 quarterly 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.

Sincerely,

Clayton A. Hixson

Clayton A. Hixson, M.D.
Director of Nuclear Medicine

Sister M. Consolata, HM.

Sister M. Consolata
Executive Director

CAH:mi
Attachments: 5

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

ATTACHMENT # 1 CONT.

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

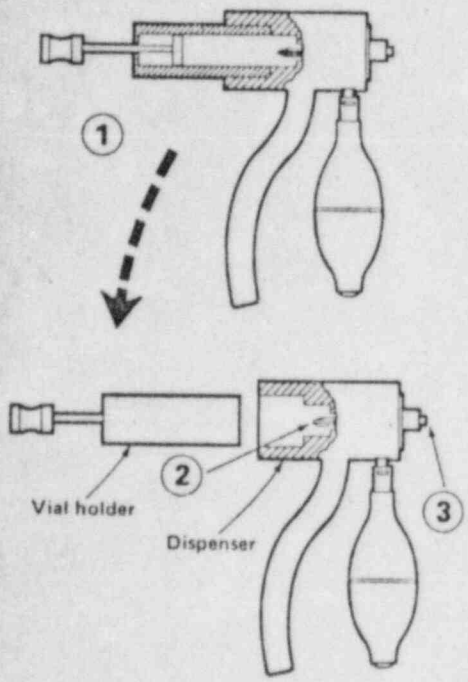
The Xenon Xe 133 gas is supplied as part of the CALIDOSE™ system, consisting of 2ml unit dose vials and the CALIDOSE dispenser* for shielded dispensing. Normally vials containing either 10 or 20mCi/vial, packed up to 5 vials per shield tube, are supplied. Vial sets containing up to 100mCi/vial are available.

*Patent Pending

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

ATTACHMENT # 2

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).

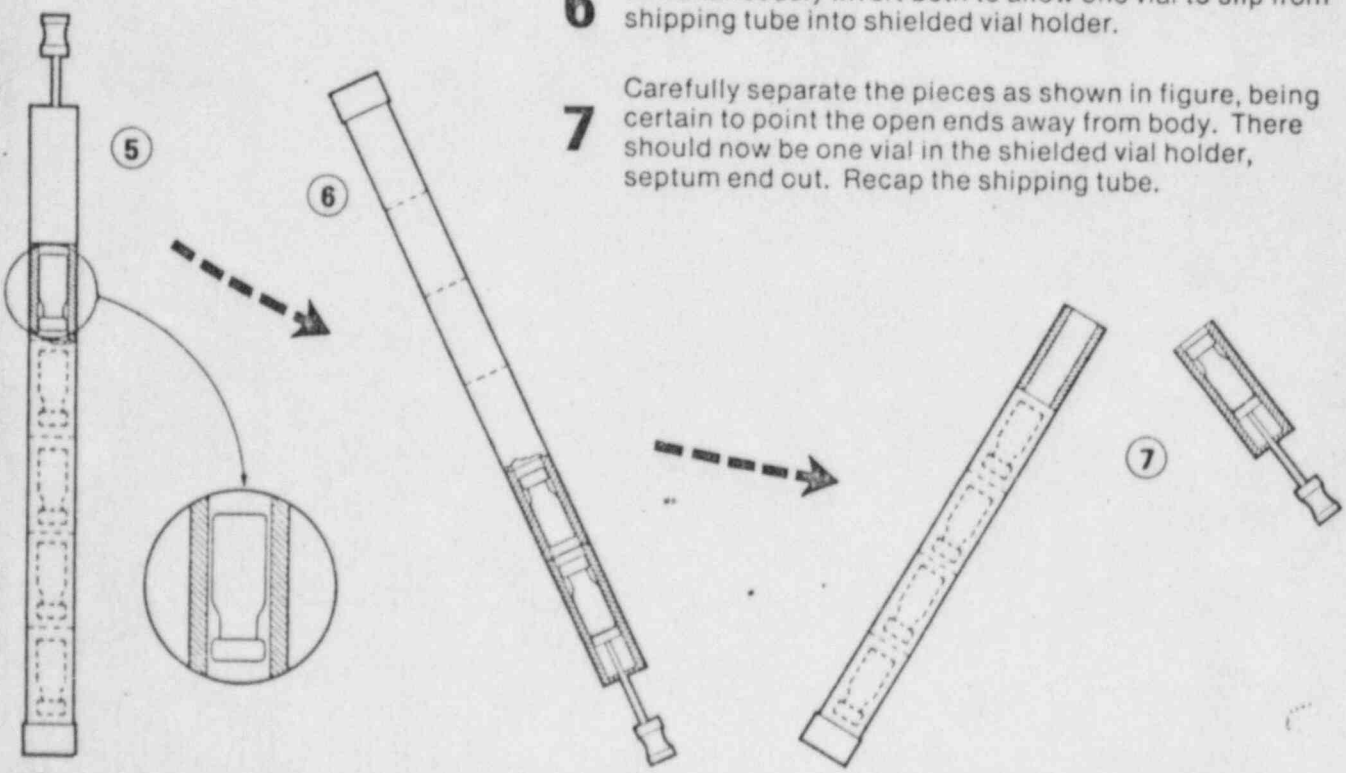
3 Attach a hypodermic needle (or other connector) securely to Luer Lock fitting on front end of dispenser.

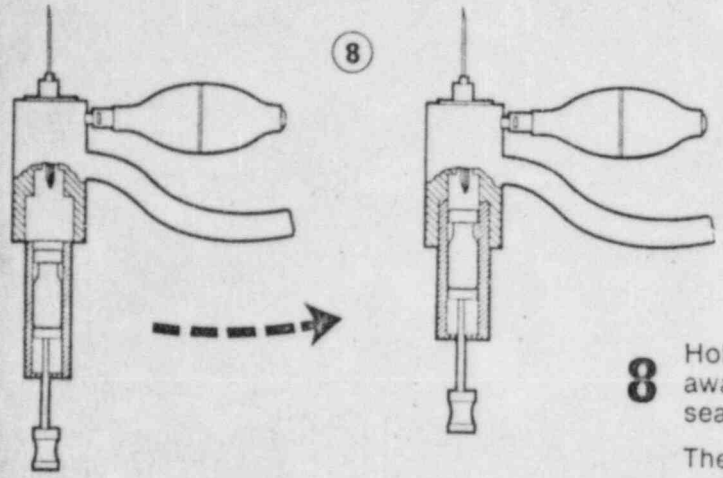
4 Remove the yellow cap of the ^{133}Xe lead shipping tube, being careful to point opened tube away from body.

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.

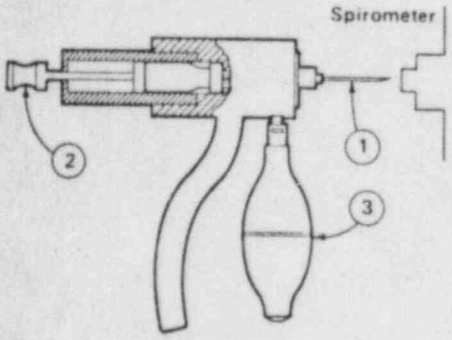




8 Holding the shielded vial holder upright (and pointed away from body), insert it into the dispenser until seated. DO NOT PUSH PLUNGER IN AT THIS TIME.

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.

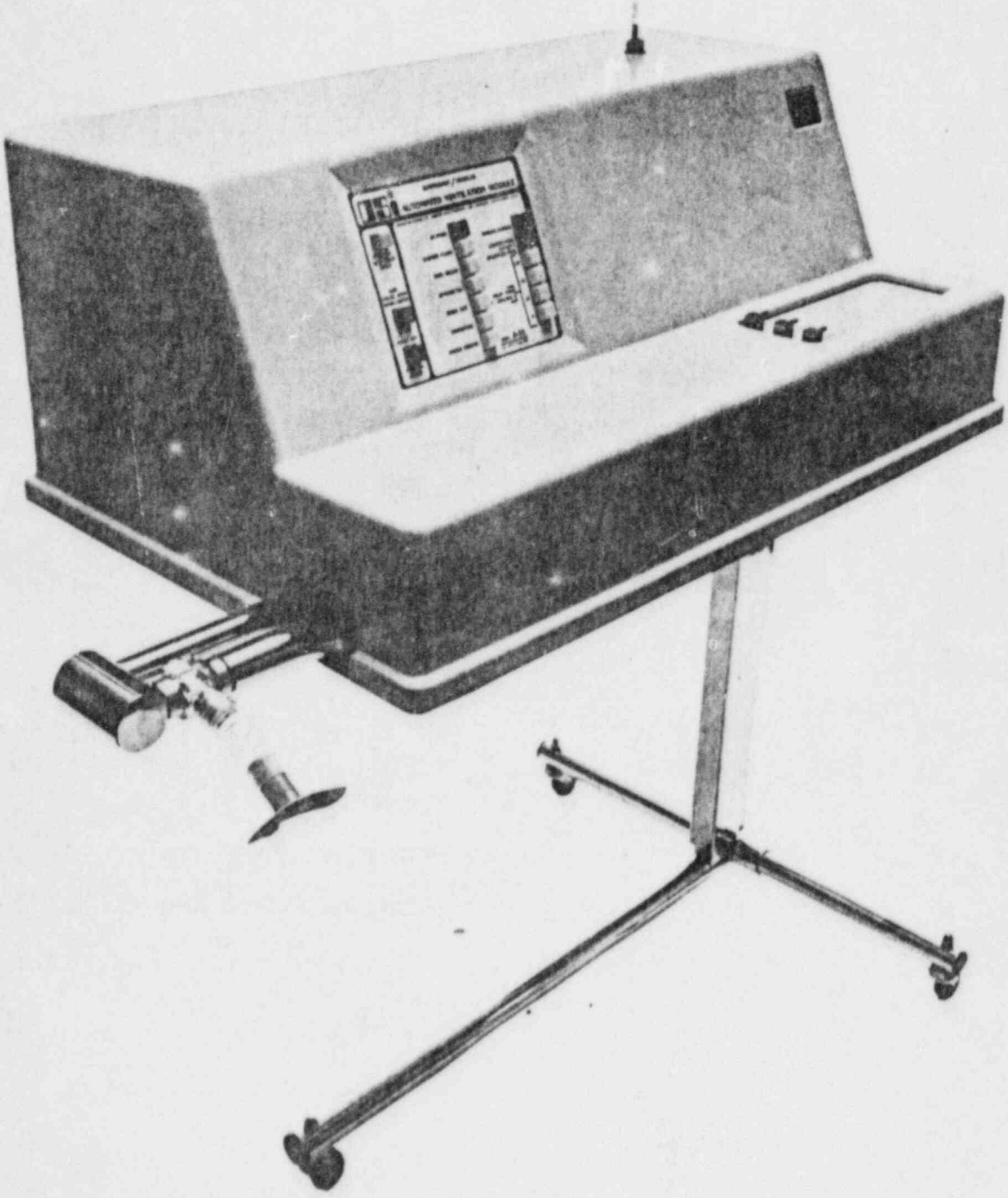
Statement

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.

ATTACHMENT # 3

Radioactive Regional Ventilation Studies

AUTOMATED VENTILATION MODULE
MODEL AVM-3



OMNIMEDICAL

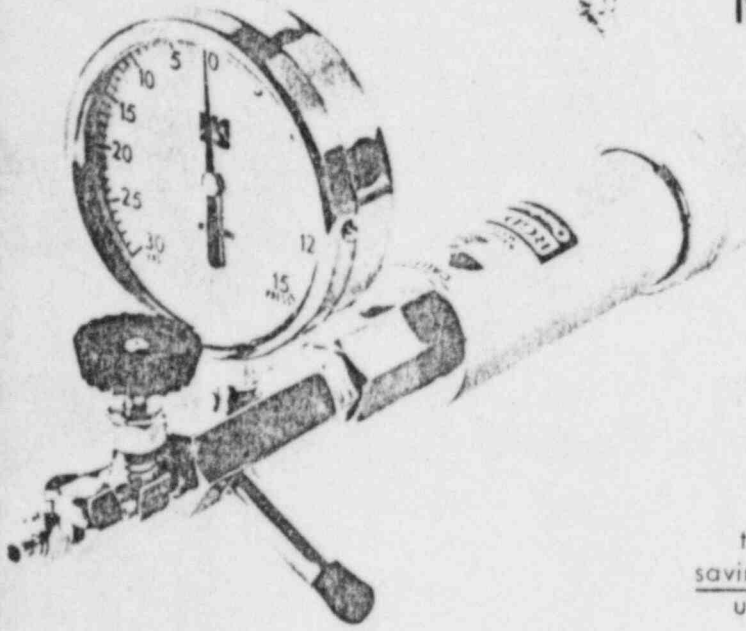
AVM-3 SPECIFICATIONS

ATTACHMENT # 3 CONTINUED

Dimensions:	33[illegible]1 ½ "x14" on 31" high stand
Electronics:	Solid state circuitry throughout system
Electrical Approval:	Approved by I.A. City Testing Labs under U.L. standards for Type B Medical and Dental Equipment
Power Requirements:	Single phase 115 volt., 60 Hz.; 3 wire grounded electrical cord
Valves:	6—24 volt D.C. solenoid valves. 1—Hans Rudolph Valve
Time Delays:	0.5, 10, 30, or 120 second intervals between scintiphotos
CO_2 A[illegible]orber:	TECO sodalime, Disposable Full Pack
Spirometer:	Dry, bellows type, 5-liter dynamic volume, calibrated displacement rod
Bolus Bladder:	2 liter
Tidal Air Bladder:	2 liter
Casters:	3" swivel, conductive rubber with front wheel locks
Net Weight:	100 pounds
Shipping Weight:	125 pounds
Patents Issued:	U.S. Patent 3,666,955

Published references available.

RADIOGAS DISPENSER MODEL RGD-700



The Radiogas [illegible] penser crushes a [illegible] stores curie ampules o xenon in its 35 ml. tan handle and allows withdrawa of single doses as needed. Th xenon ampule is crushed AFTER th tank is sealed and the gas is then store at atmospheric pressure for ease in with drawing single doses (according to the vo ume formula) while reducing the chance o accidental leaks.

General Electric, Vallecitos Nuclear Center provide the first curie ampule at no charge and subsequen savings over single dose purchases are significant. At a vo ume of 20 studies per month, the savings would pay fo the Radiogas Dispenser after the first seven procedure

All products carry a full one year warranty covering labor and defective parts.

PRICES

Automated Ventilation Module (AVM-3)	$3375.00
Radio gas Dispenser (RGD-700	275.00

Products are shipped F.O.B. Los Angeles, California. Terms: Net 30 days.

OMNIMEDICAL SERVICES, INC.

3711 LONG BEACH BLVD. LONG BEACH, CALIF. 90807 (213) 595-1658

OPERATIONAL MODES—AUTOMATIC SEQUENCING

ATTACHMENT # 3 CONTINUE

Xenon ventilation studies are initiated on the AVM-3 in one of four operational modes: Single Breath, Rebreathe, Spirometer, or Spirometer/Bolus. In Single Breath mode, the single breath study is followed automatically with a washout study. In Rebreathe mode and Spirometer/Bolus mode, a single breath study is automatically obtained followed by a rebreathe study. In the latter two modes, as well as Spirometer mode, a washout study is obtained by simply pressing the Washout button. Each of the four operational modes provides the clinician with full flexibility in technique for performing ventilation studies.

Reprogramming of the AVM-3 is necessary only if the desired technique is changed. Once the operational mode, lung volume and Time Delay (between scintiphotos) have been selected, ONLY the Start (or Gas Release) and Washout buttons need be pressed to complete a study.

Single Breath Mode

In Single Breath mode, the AVM-3 administers a premeasured bolus of xenon followed automatically by air from the Tidal Air bladder or from atmosphere to the patient's vital capacity. The scintillation camera is electronically signaled to begin the first scintophoto at the conclusion of the inspiration and the valves close to prevent the patient from exhaling. (The length of the breath hold period is determined by the pre-set time or counts on the scintillation camera.) When the first scintiphoto is completed, the valves open automatically to atmosphere and exhaust and washout scintiphotos are initiated. Single breath studies may also be performed at any lung volume with a xenon bolus or xenon dispersed throughout the inspiration (see Spirometer/Bolus and Spirometer modes).

Rebreathe Mode

In Rebreathe mode, a single breath scintiphoto is obtained automatically. When the single breath scintiphoto is completed, the valves open to a closed rebreath system utilizing the AVM-3's 5-liter Spirometer and an in-line CO_2 absorber. When sufficient rebreathe scintiphotos have been obtained (the patient has reached equilibrium), the technologist presses the Washout button, opening the atmosphere and exhaust valves. Oxygen may be added to the spirometer at any time before or during the procedure.

Spirometer/Bolus Mode

The Spirometer/Bolus mode is designed to allow the technologist to observe patient respiration on the spirometer and press the Gas Release button to administer a bolus of xenon at any point during inspiration. After the bolus has been administered, single breath, rebreathe and/or washout studies are obtained as described above.

Spirometer Mode

In Spirometer mode, the patient receives radioxenon dispersed throughout the first inspiration from the spirometer. As in the other modes, single breath, rebreathe and/or washout studies may be obtained.

In all operating modes, the patient breathes ambient air through the system using the atmosphere and exhaust valves prior to the initiation of the study.

ELECTRONIC CAMERA INTERFACE

Only the AVM-3 is completely automated including electronic interfacing with scintillation cameras (any make or model) to allow programmed start, stop and reset signals to be exchanged between the AVM-3 and the camera. It does more than remotely operate the camera; the AVM-3 is programmed to start the scintillation camera at the conclusion of the single breath inspiration, to automatically sequence modes when the camera has reached its preset time or counts; and to reset and start the camera again at the end of the programmed Time Delays. It is never necessary to start or reset the camera manually during a lung ventilation study using the AVM-3. Electronic interface enables one technologist to easily perform the entire ventilation study and allows accurate reproducibility of study data.

SUMMARY OF AVM-3 FEATURES

CLINICAL CAPABILITIES

* Single Breath Studies
  Performed at premeasured Tidal Volume or Vital Capacity.
  Radioxenon in bolus or dispersed throughout inspiration.
    Bolus variable in concentration and volume.
    Bolus administration at any selected point during inspiration.
  Single Breath followed automatically by Rebreathe and/or Washout.
* Rebreathe Studies
  Resistance/assistance free closed system with CO_2 absorber.
  Separate spirometer fill valve for oxygen replenishment.
  Calibrated spirometer displacement rod on 5-liter spirometer.
* Washout Studies
  Resistance/assistance free atmosphere to patient to exhaust.
* Patient Positioning
  Adjustable for obtaining any view in any position.

FUNCTIONAL CHARACTERISTICS

* Electronic camera interface for programmed start-stop-reset.
* Fully automated mode sequencing.
* Push button xenon administration.
* Minimal deadspace for bolus administration of xenon.
* 180° mouthpiece rotation at elevations of 31" to 46" from floor.
* Single enclosed module, free standing on casters.
* Light compact and portable for convenient storage.
* Lead shielding for personnel and patient protection.
* Suction controlling exhaust outlet.

The Surprenant/Douglas Automated Ventilation Module is the product of over 3 years of development and extensive clinical testing. The objective was to enable clinicians to perform Radioxenon lung ventilation studies as effectively and conveniently as possible. The result is an instrument that incorporates versatility, true automation, electronic camera interface and simplicity into a clinically effective xenon administration system.

VERSATILITY OF OPERATING MODES

Single Breath, Rebreathe and Washout studies can all be easily performed with the AVM-3. The AVM-3 enables single breath studies to be performed at Tidal Volume or Vital Capacity using either a bolus of xenon or xenon dispersed throughout the inspiration. The bolus of xenon may be of any volume and concentration and can be administered at the beginning or any subsequent point during the patient's inspiration. Single breath studies can be performed without active patient cooperation.

ATTACHMENT # 4

OMNIMEDICAL

RADIOACTIVE GAS TRAP
MODEL GT-10

REFRIGERATED:	Temperature (approx. 40°F)	
TRAPPING AGENT:	Charcoal, Coconut Activated (8-12 mesh)	
# OF STORAGE CYLINDERS:	2 in series for Charcoal 1 of Silica Gel	
CYLINDER DIAMETER:	2 inches	
CYLINDER LENGTH:	13 inches	
SIZE OF CABINET:	Height Width Depth	22 inches 19 inches 19 inches
POWER REQUIRMENTS: on-off (pump) on-off (refrigeration)	 500 watts (max.), 120 vac., 60 Hz maximum 500 watts, 120 vac.	
AIR FLOW:	20 liters/minute	
SHIELDING:	The cabinet is partially shielded with 1/16 inch lead. All compartments internally shielded with 1/8 inch lead.	
EFFECTIVE EFFICIENCY:	95%	

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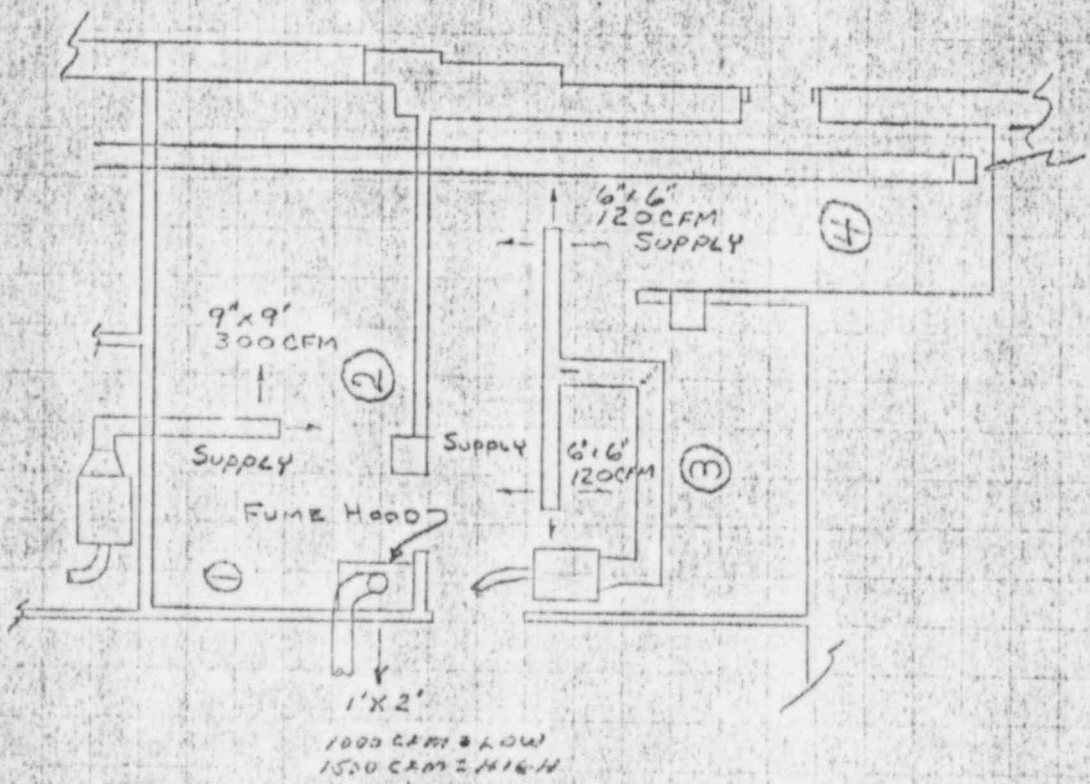
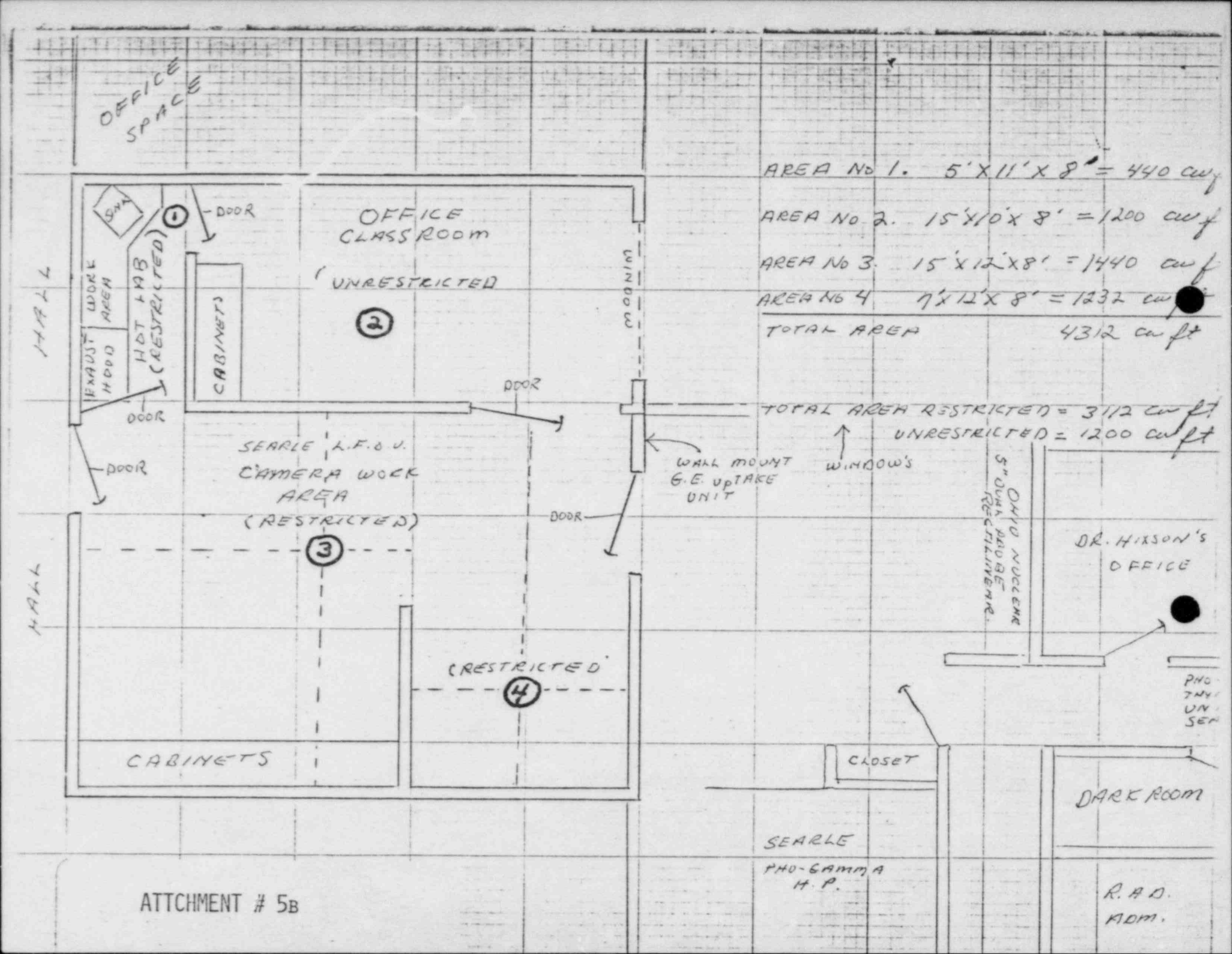


ATTACHMENT # 5A



ATTCHMENT # 5B

ATTCHMENT # 5c