

FORM NRC-313M 7-77 10 CFR 30	U.S. NUCLEAR REGULATORY COMMISSION <b>APPLICATION FOR MATERIALS LICENSE - MEDICAL</b>																																													
<p><b>INSTRUCTIONS:</b> Complete items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Mail two copies to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a NRC Materials License. A NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20, and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.</p> <p style="text-align: right; font-size: 1.2em;">030-14772</p>																																														
1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE  Veterans Administration Hospital 7th St. and Indian School Rd. Phoenix, Arizona 85012  TELEPHONE NO.: AREA CODE 602, 277 5551	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE  Veterans Administration Hospital 7th St. and Indian School Rd. Phoenix, Arizona 85012  L10072 02120																																													
2. PERSON TO CONTACT REGARDING THIS APPLICATION  Joseph J. Likos, M.D. TELEPHONE NO.: AREA CODE 602, 277 5551	3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input type="checkbox"/> AMENDMENT TO LICENSE NO. _____ c. <input checked="" type="checkbox"/> RENEWAL OF LICENSE NO. 02-10072.01																																													
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.) a) Joseph J. Likos, M.D. 1-5 b) George F. Lull Jr., M.D. 2-4 c) John B. Byrne, M.D. 1 d) W. Well Bretherton, M.D. 1 e) Jay LeGrand, M.D. 1-3	5. RADIATION PROTECTION OFFICER (Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Supplement A.)  Joseph J. Likos, M.D. (Resume: Refer to license #02-10072.01)																																													
6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE																																														
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6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Small sealed sources (up to 3m Ci) used for calibration and reference standards are authorized under Section 35.74(d), 10 CFR Part 35, and NEED NOT BE LISTED.)																																														
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# INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

Submit a detailed description of all the information requested in Items 7 through 23. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right hand corner of each page. Two copies of each appended sheet should be submitted with the application.

## 7. MEDICAL ISOTOPES COMMITTEE.

- a. Committee's Duties and Responsibilities.
- b. Meeting Frequency.
- c. Name and Specialty of Each Committee Member.

## 8. TRAINING AND EXPERIENCE.

- a. Authorized User(s). *(Each physician must complete Supplements A and B.)*
- b. Radiation Safety Officer.  
*(Complete Supplement A, if other than a physician already listed.)*

## 9. INSTRUMENTATION. *(List by manufacturer's name and model number.)*

- a. Survey Instruments.
- b. Dose Calibrator.
- c. Diagnostic Instruments.
- d. Other *(e.g. liquid scintillation counter, area monitor.)*

## 10. CALIBRATION OF INSTRUMENTS.

- a. Methods.
- b. Frequency.
- c. Standards (Radionuclide and Activity).

## 11. FACILITIES AND EQUIPMENT. *(Complete description and diagram.)*

## 12. PERSONNEL TRAINING PROGRAM AND FREQUENCY.

## 13. PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL.

## 14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL.

## 15. GENERAL LABORATORY RULES FOR THE SAFE USE OF RADIOACTIVE MATERIALS.

## 16. EMERGENCY PROCEDURES, INCLUDING NAMES AND TELEPHONE NUMBERS OF PERSONNEL TO BE NOTIFIED.

## 17. AREA SURVEY PROCEDURES.

## 18. WASTE DISPOSAL PROCEDURES.

## 19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS.

- a. Procedures
- b. Precautions.
- c. Personnel Instructions.

## 20. THERAPEUTIC USE OF SEALED SOURCES.

- a. Procedures.
- b. Precautions.
- c. Personnel Instructions.

## 21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES. *(e.g., xenon-133)*

## 22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS.

## 23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.B.

NOTICE  
U.S. NUCLEAR  
COMMISSION  
SECTION  
REC.

07 11 AM  
SEP 12 1978

7. MEDICAL ISOTOPES COMMITTEE

The committee's duties and responsibilities and meeting frequency are as described in Appendix B, NUREG - 0338, Rev. 1 dated 11/1/77.

Item No. 7  
Date: 8/25/78

~~SC401~~

8. TRAINING & EXPERIENCE

1. Joseph J. Likos, M.D. (Radiation Safety Officer)
2. George F. Lull Jr., M.D.
3. John B. Byrne, M.D.
4. W. Wells Bretherton, M.D.

Refer to training and experience as outlined in previous license  
# 02-10072-01 for above-named individuals.

5. Jay LeGrand, M.D.: American Board of Nuclear Medicine certification  
# 03668, 10/27/76.

Item No. 8  
Date: 8/25/78

APPENDIX C

INSTRUMENTATION

9.(1) Survey Meters

a. Manufacturer's Name: Nuclear Chicago

Manufacturer's model number: 2650

Number of instruments available: 1

Minimum Range: .01 mr/hr to 0.1 mr/hr

Maximum Range: 0.1 mr/hr to 100 mr/hr

b. Manufacturer's Name: Atomic Products

Manufacturer's model number: 051-74F

Number of instruments available: 1

Minimum Range: 0 mr/hr to 25 mr/hr

Maximum Range: 0 mr/hr to 25000 mr/hr

Item No. 9  
Date: 8/25/78

9.(2) Dose Calibrator

Manufacturer's Name: Capintec

Manufacturer's model number: CRE-30

Number of instruments available: 1

9.(3) Diagnostic Instruments

<u>Type of Instrument</u>	<u>Manufacturer's Name</u>	<u>Model No.</u>
Gamma Camera (1)	Searle	LFOV
Gamma Camera (2)	Searle	LFOV
Rectilinear Scanner	Picker	5" Magna Scanner
Well-Counter Scanner	Picker	Spectroscaler 4R

9.(4) Primalert-50 (3) Nuclear Associates, Inc. 085-431

Personal Radiation Monitor (3) Atomic Products

Model # 052999



10a.

CALIBRATION OF SURVEY INSTRUMENTS

1. Survey instruments will be calibrated at least annually and following repair.
2. Survey instruments will be calibrated by an outside firm.

ARADTEK  
8301 S. Terrace  
Tempe, Arizona 85204

Procedures and sources have been approved by NRC and are on file in License No. Arizona AEC # 10-55.

Item No. 10a  
Date: 8/25/78

10b.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test:

First elution from new Mo-99/Tc-99m generator

B. Sources Used for Instrument Accuracy and Constancy Tests:

<u>Radionuclide</u>	<u>Activity</u> (mCi)	<u>Accuracy</u>
57 Co	3 mCi	5%
Ra <sup>226</sup>	14.4 uCi	9.3%

C. The procedures described in Appendix D Section 2 will be used for calibration of the dose calibrator.

Item No. 10b

Date: 8/25/78

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10c. DIAGNOSTIC INSTRUMENTS

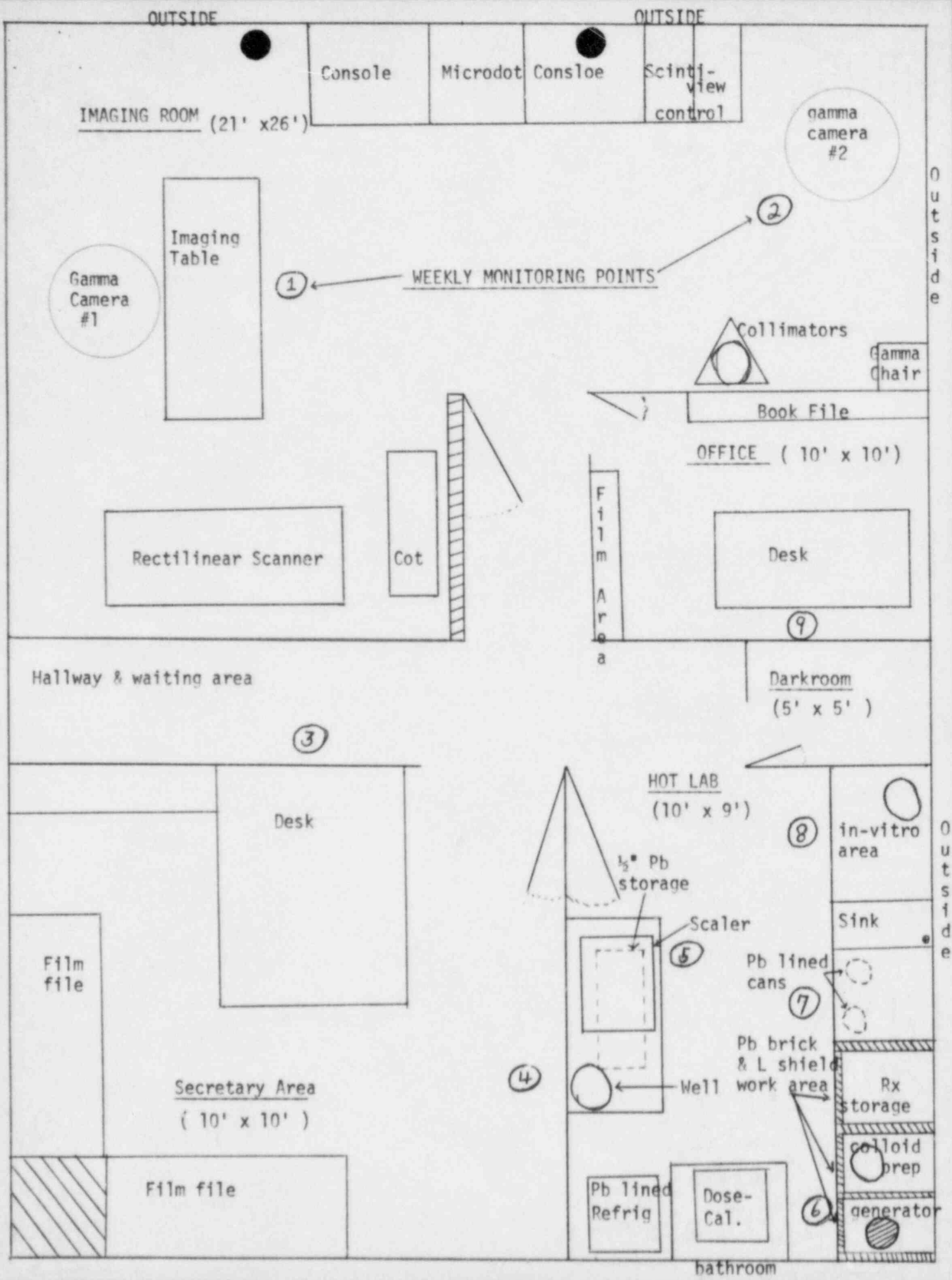
Manufacturer's directions will be followed for calibration  
and maintenance of diagnostic instrumentation.

Item No. 10c  
Date: 8/25/78

11. FACILITIES & EQUIPMENT

Hot lab is the designated area for receipt, storage, preparation, and measurement of radioactive material. (See attached diagram)

Item No. 11  
Date: 8/25/78



12. PERSONNEL TRAINING PROGRAM

At the present time, we have two registered Nuclear Medicine technologists handling all radioactive materials. They have 15 plus years of experience in handling radioactive materials and update their training with annual refresher courses held by local civil defense authorities. They are well informed of pertinent NRC regulations and terms of our NRC license.

Item No. 12

Date: 8/25/78

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

All radioactive materials are ordered by Chief of Nuclear Medicine or by the Chief Technologist of Nuclear Medicine Department, which ensures that possession limits are not exceeded. All packages are received by the Department of Nuclear Medicine, except after hours and on weekends, in which case the security guards are instructed to sign for the packages and place them, unopened, in designated area in the Nuclear Medicine Department. The next working day, the packages are leak-tested and opened by personnel in the department of Nuclear Medicine.

Item No. 13  
Date: 8/25/78

14. PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Procedures described in Appendix F are complied with.

Item No. 14

Date: 8/25/78



15.

LABORATORY RULES FOR THE USE OF RADIOACTIVE MATERIAL

Laboratory rules as stated in Appendix G are complied with.

Item No. 15

Date: 8/25/78

16. EMERGENCY PROCEDURES

Emergency procedures as outlined in Appendix H will be complied with.

17. SURVEY PROCEDURES

We will comply with monitoring procedures as outlined in Appendix I.

18.

APPENDIX J

WASTE DISPOSAL PROCEDURES

1. Liquid waste will be disposed of in the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.
2. Mo-99/Tc-99m generators will be returned to the manufacturer for disposal.
3. Other solid waste will be returned to local supplier Nuclear Pharmacy Inc., Phoenix, Arizona.

Item No. 18

Date: 8/25/78

19. PROCEDURES FOR USE OF GROUPS IV AND V RADIOPHARMACEUTICALS  
FOR TREATMENT OF PATIENTS

Will follow procedures described in Appendix K.

Item No. 19  
Date: 8/25/78

20. THERAPEUTIC USE OF SEALED SOURCES

Not applicable.

Item No. 20  
Date: 8/25/78



21. The following information is submitted in support of our request to use Xenon-133.

a. Quantities to be Used:

(1) Patient information

- (a) 3 studies per week
- (b) 10 mCi per study

(2) 500 mCi

b. Use and Storage Areas:

(1) Xenon will be used in the imaging room (see diagram attached) and stored in lead storage chest until use.

(2) See attached diagram.

(3) Engineering Department will check air flow rates at least semi-annually.

c. Procedures for Routine Use:

(1) Manufacturer's suggested safety procedures as outlined in product information brochure will be strictly adhered to.

(2) See attached brochure.

(3) All studies will be done using disposable air-tight full face and nose masks.

d. Emergency Procedures:

In case of accidental spillage of Xenon 133, the area will be evacuated and closed; exhaust system air flow will be increased until level of radiation reaches background.

e. Air Concentrations of Xenon-133 in Restricted Areas:

Imaging room contains 3 inlet and 3 outlet ducts. (See attached diagram) Incoming air is 290 cfm total, and outgoing air volume is 330 cfm. Doing an average of 3 patients weekly and 10 mCi per study, we calculate the amount that can be released per week without exceeding the average concentration of  $3 \times 10^7$  uCi/ml would be 28.4 mCi of Xenon-133 per week, which is well below the actual amount released.

Item No. 21

Date: 8/25/78

f. Methods of Xenon-133 Disposal:

- (1) Unused supplies of Xenon-133 will be returned to local supplier, Nuclear Pharmacy Inc., Arizona license 7-123.
- (2) Charcoal trap used as described in attached brochure.

2. Absorption onto Charcoal Traps:

- (ii) Xenon-133 trap will be monitored after each study and when appreciable rise in radiation levels are detected. The charcoal cartridge will be placed, as prescribed by manufacturer's detailed operating instructions, in lead-lined storage containers (See attached diagram) and a new cartridge placed in the trap.

Item No. 21

Date: 8/25/78

# Atomlab

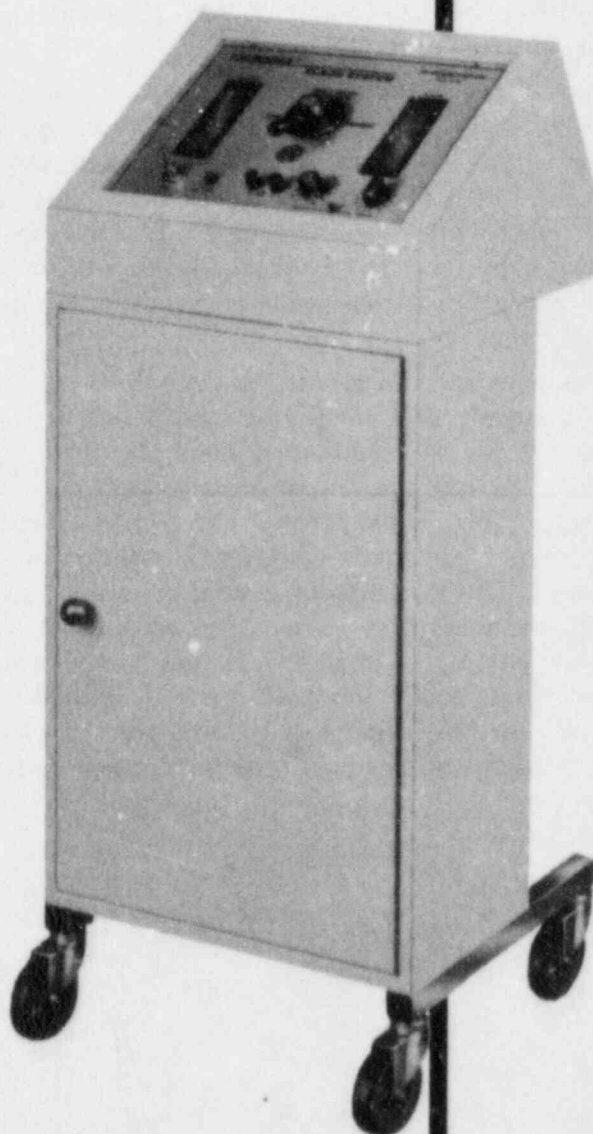
Full-function xenon delivery system with built-in xenon gas trap for rebreathing, washout, perfusion and single breath studies on supine or seated patients.

# PULMONEX XENON SYSTEM

with integrated GAS TRAP.

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

- 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.



## Atomic Products Corporation

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

The Pulmonex Xenon System is a simple to use, reliable and complete system for the performance of 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 patient 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 automatically 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 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<sub>2</sub> 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 expanded.

#### **Specifications:**

Motor UL approved. 115 VAC, 50/60 Hz.  
Size: 18" x 19" x 46"  
Weight: 150 lbs.

130-500 Pulmonex Xenon System . . . . . \$ 2495.00  
127-318 Replacement Charcoal  
Cartridge for Gas Trap . . . . . 200.00

□ MR IN 290 cfm

▣ AIR OUT 330 cfm

IMAGING ROOM  
(5460 cu ft)

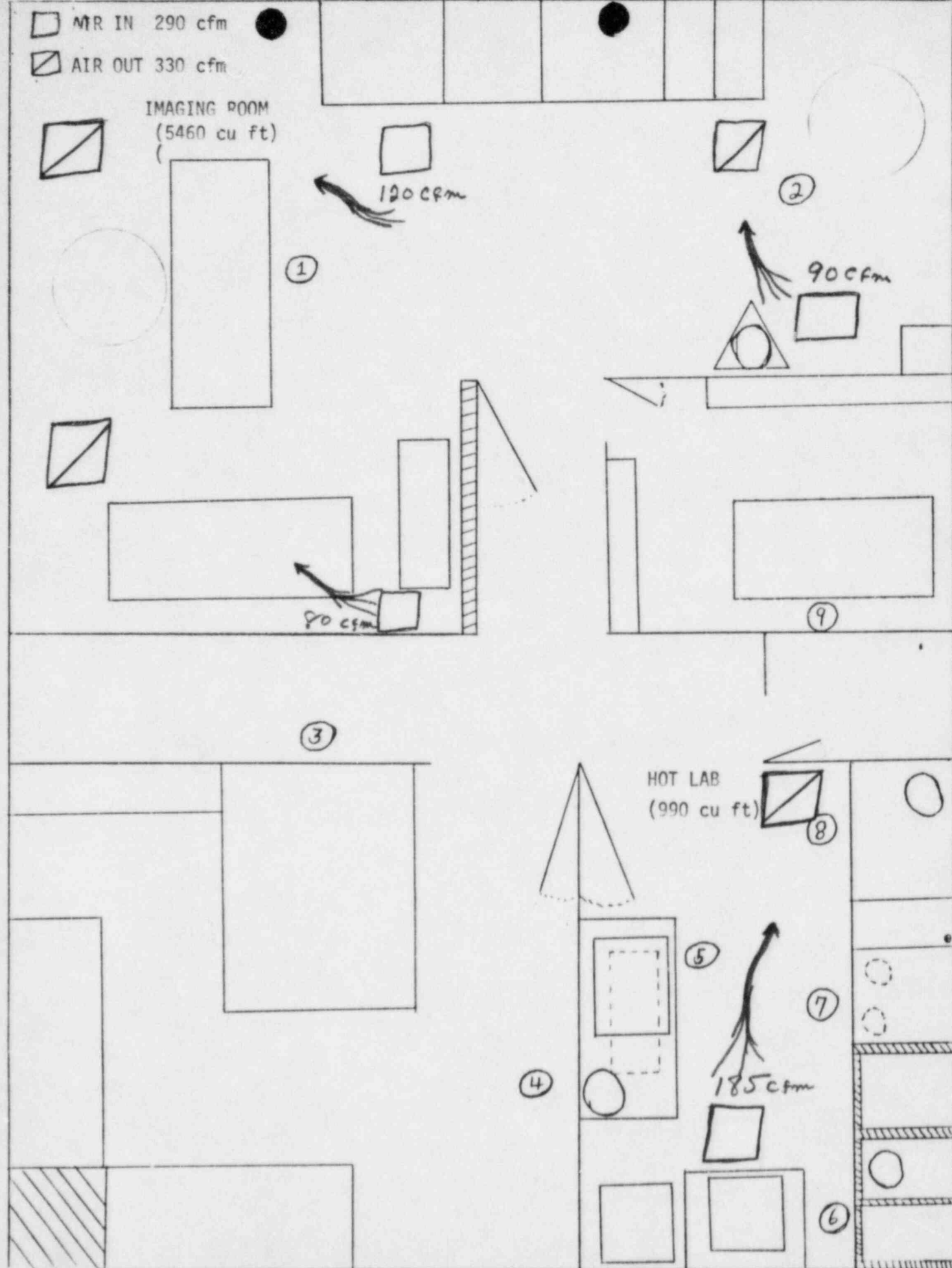
120 cfm

90 cfm

80 cfm

HOT LAB  
(990 cu ft)

185 cfm



OUTSIDE

OUTSIDE

Outside

Outside

IMAGING ROOM (21' x 26')

Console

Microdot

Console

Scintiview control

gamma camera #2

Imaging Table

Gamma Camera #1

WEEKLY MONITORING POINTS

Collimators

Gamma Chair

Book File

OFFICE (10' x 10')

Rectilinear Scanner

Cot

Desk

Hallway & waiting area

Darkroom (5' x 5')

Desk

Film file

Secretary Area (10' x 10')

Film file

HOT LAB (10' x 9')

1/2" Pb storage

Scaler

Pb lined cans

Pb brick & L shield

Well work area

in-vitro area

Sink

Rx storage

colloid prep

generator

Pb lined Refrig

Dose-Cal.

Bathroom



22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIALS IN ANIMALS

Not applicable.

Item No. 22

Date: 8/25/78

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED  
IN ITEM 6B

Items listed in 6b (thallium-201 for cardiac imaging, NEN and I-123 for thyroid imaging, medi-physics are accepted and approved by the FDA and will be used in accordance with the federal Food, Drug, and Cosmetics Act and the Public Health Service Act. Also specific instructions as outlined in the manufacturer's product brochure will be strictly complied with.

Item No. 23  
Date: 8/25/78

# 24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	<input checked="" type="checkbox"/> FILM	Searle Analytic Des Plaines, Illinois 60018	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		
b. FINGER	<input type="checkbox"/> FILM		
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		

c. OTHER (Specify)

Personal Radiation Monitors (2) - Atomic Products Model # 052999

## 25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.
NAME OF HOSPITAL		
MAILING ADDRESS		c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.
CITY	STATE ZIP CODE	

## 26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED (See Section 170.31, 10 CFR 170)	b. APPLICANT OR CERTIFYING OFFICIAL (Signature)
	(1) NAME (Type or Print) Joseph J. Likos, M.D.
(1) LICENSE FEE CATEGORY:	(2) TITLE Chief, Laboratory & Nuclear Medicine
(2) LICENSE FEE ENCLOSED: \$	c. DATE 8/26/78

# TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION PROTECTION OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION PROTECTION OFFICER

2. STATE OR TERRITORY IN  
WHICH LICENSED TO  
PRACTICE MEDICINE

## 3. CERTIFICATION

SPECIALITY BOARD  
ACATEGORY  
BMONTH AND YEAR CERTIFIED  
C

## 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING  
ALOCATION AND DATE(S) OF TRAINING  
B

TYPE AND LENGTH OF TRAINING

LECTURE/  
LABORATORY  
COURSES  
(Hours)  
CSUPERVISED  
LABORATORY  
EXPERIENCE  
(Hours)  
Da. RADIATION PHYSICS AND  
INSTRUMENTATION

b. RADIATION PROTECTION

c. MATHEMATICS PERTAINING TO  
THE USE AND MEASUREMENT  
OF RADIOACTIVITY

d. RADIATION BIOLOGY

e. RADIOPHARMACEUTICAL  
CHEMISTRY