10/31 - ACS

Woodland Medical Group, P.C.

October 14, 1980

USNRC
Office of Inspection and
Enforcement
799 Roosevelt Road
Glen Ellyn, IL 60137
ATTENTION: John Cooper

030-02149

2/28/85
7B

Dear Dr. Cooper:

Please amend license No. 21-13255-01 to include byproduct material use at our Novi Office (41935 W. Twelve Mile Road) as well as at our present office (22341 W. Eight Mile Road).

Attached is additional information for judging the safety of our operation. General radiation safety will be as described in our current application (Form NRC-313M plus attachments on file).

In addition, please amend our license to include the use of a 12 mCi (± 15%) Americium -241 sealed source (Model AMC 24 Amersham Corporation) for anatomical marking.

Also attached is our signed ALARA program and a $40 check for the ammendment fee (category 7.C.).

Thank you for your assistance.

Sincerely,

Barry I. Samuels, M.D.

Barry I. Samuels, M.D.

BIS/kj
Encs.

RECEIVED BY LFMB
OCT 2 8 1980
Date
Log Oct. P62314
By Broom
Orig. To
Action Compl 10/30/80

Applicant's check 21970 $40 (7B)
Amount
Date
Received by Broom
OCT 28 1980

A/31
OCT 20 1980

Control No. 03993

22341 WEST EIGHT MILE RD. • DETROIT, MICHIGAN 48219 • PHONE: 538-4700

10/31 - DCS

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557

INSTRUCTIONS – *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. Retain one copy. Submit original and one copy of entire application 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 Materials License. An 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.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Woodland Medical Group
22341 West Eight Mile Road
Detroit, Mi 48219

TELEPHONE NO.: AREA CODE (313) 538 4700

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

22341 West Eight Mile Road
Detroit, Mi 48219
and
41935 West Twelve Mile Road
Novi, Mi 48050

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Liz Taylor

TELEPHONE NO.: AREA CODE (313) 538 4700

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 21-13255-01
c. ☐ RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Barry Samuels, M.D.
Harold Daitch, M.D.
Richard Small, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Barry Samuels, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	3
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000
10 CFR 35.100,SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries,
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	30 capsule
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	10
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	200

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Americium-241	sealed source (Amersham Corp. Model AMC.24)	14	Imaging Marker

OCT 2[illegible] 1990

Control No. 03993

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: January 1979

7. MEDICAL ISOTOPES COMMITTEE N.A.	
	Names and Specialties Attached; and
	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE see previous application	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM see previous application	
	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL see previous application	
	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)* see previous application	
	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R. S. Landauer, Jr. & Co.	monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, Jr. & Co.	monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL: see previous license application

MAILING ADDRESS:

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

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, Parts 30 and 35, 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)*

(1) LICENSE FEE CATEGORY: 7.c.

(2) LICENSE FEE ENCLOSED: $ 40.

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*: Barry I. Samuels, M.D.

(1) NAME *(Type of Print)*: Barry I. Samuels, M.D.

(2) TITLE: Director, Nuclear Medicine & Ultrasound

c. DATE: 10-14-80

FORM NRC-313M (8-78)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

SUPPLEMENTAL SHEETS

Item 7. MEDICAL ISOTOPES COMMITTEE

N.A.

Item 8. TRAINING AND EXPERIENCE

Individual users previously licensed on License No. 21-13255-01.

Item 9. INSTRUMENTATION

See attached APPENDIX C

Item 10. CALIBRATION OF INSTRUMENTS

See attached APPENDIX D

Item 11. FACILITIES AND EQUIPMENT

A. Facilities:

(see attached diagram)

B. Equipment:

For Health Physics and Clinical Instrumentation see Item 9.

For reducing internal exposures, disposable gloves, absorbent pads, etc. will be used.

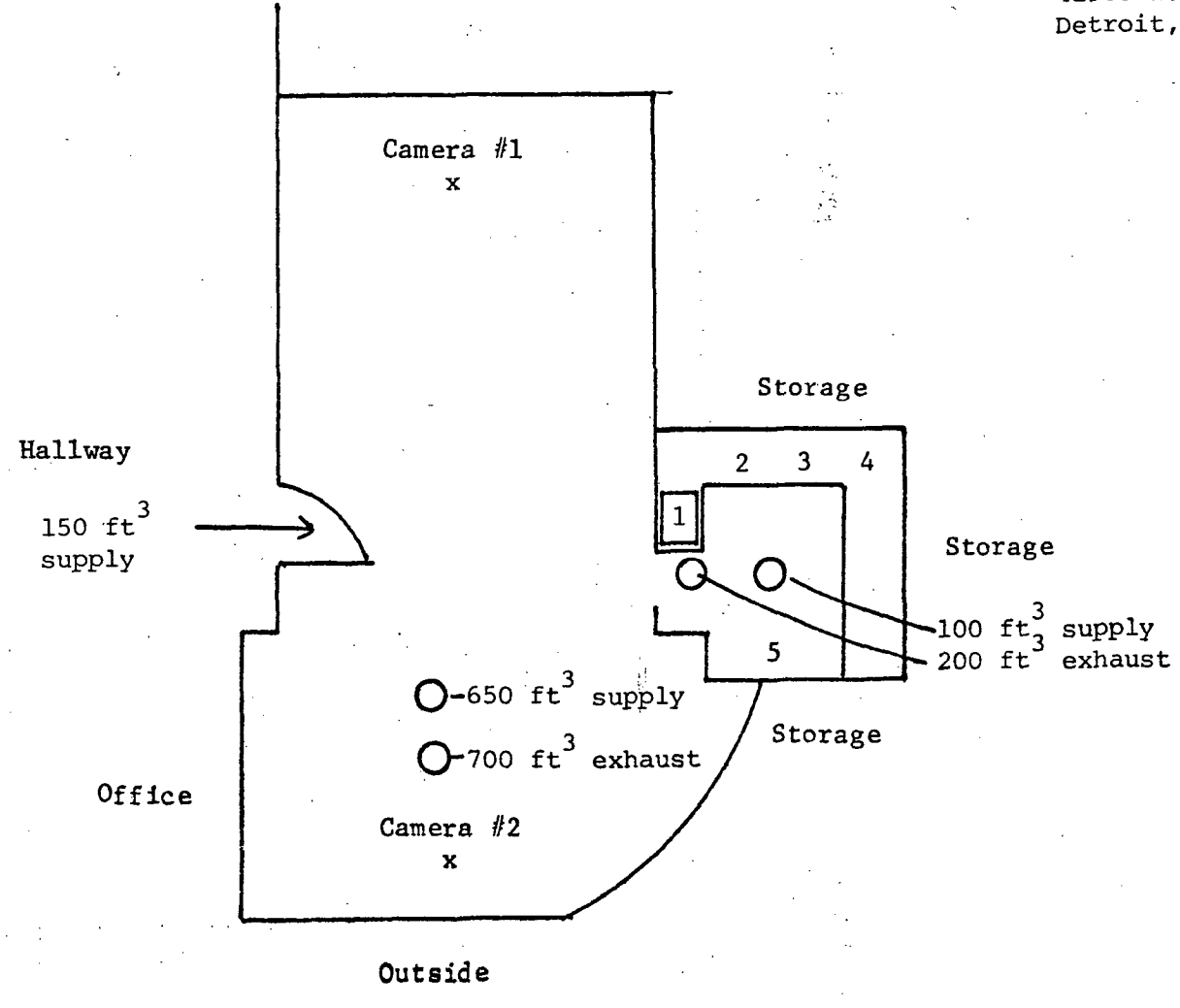
For reducing external exposures, remote handling devices, shielding (lead bricks, lead glass "face" shield, syringe holders, lead "pigs will be used. Syringe shields will be used when the use does not interfer with patient care (e.g. in the case of difficult injectior

Item 12. PERSONNEL TRAINING PROGRAM

All personnel will receive proper instruction in the items specified in 19.12 of 10CFR Part 19, including items a through j page 10.8-6 of REGULATORY GUIDE 10.8.

Personnel will be instructed initially, at least annually through refresher training, and whenever the scope of the training changes significantly.

Woodland Medical Group
Novi Office
41935 W. Twelve Mile Road
Detroit, Mi 48050



1. Sink
2. Radioactive Package Receipt and Unpackaging
3. "Dose" Preparation (Lead-Glass Face Shield)
4. Mo-99/Tc-99m Generator (Lead Shielding)
5. Waste Storage (Shielded)

Note: 1. Nearest occupied area to exhaust is room below (exhaust is on roof).
2. Nearest intake vent is greater than 100 feet from exhaust vent.
3. The air from Nuclear Medicine is not recirculated.
4. Additional air joins the air from Nuclear Medicine before exhaust on

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Eberline

   Manufacturer's model number: E-120

   Number of instruments available: 1

   Minimum range: 0 mr/hr to .5 mr/hr

   Maximum range: 0 mr/hr to 50 mr/hr

   b. Manufacturer's name: Eberline*

   Manufacturer's model number: E-520

   Number of instruments available: 1

   Minimum range 0 mr/hr to .2 mr/hr

   Maximum range 0 mr/hr to 2000 mr/hr

   * Needed for high range with Mo-99/Tc-99m generator. Will be available when generator used. It will not be available if we elect not to use a generator and unit dose instead (Pharmatopes).

2. Dose calibrator

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC-4

   Number of instruments available: 1

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	G.E.	Maxi 4
Thyroid Uptake System	Picker	Spectroscaler 4 + 2 x 2" crystal
Well Counter	To be purchased	

4. Other

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

x 1. Survey instruments will be calibrated at least annually and following repair.

x 2. Calibration will be performed at two points on each scale (used).

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ±10% of the calculated or known values for each point checked. Readings within ±20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

3. Survey instruments will be calibrated

____ a. By the manufacturer

____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
Accuracy _____
Traceability to primary standard _____

____ (2) The calibration procedures in Section I of Appendix D will be used

or

____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

x c. By a consultant or outside firm

(1) Name Medical Physics Consultants

(2) Location Ann Arbor

(3) Procedures and sources

____ have been approved by NRC and are on file in License No. _____

x are attached Procedures as in Appendix D Section I (attached)
Instrument Calibrator-Victoreen 681A

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

x — Other* (specify) highest activity used

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Activity (mCi)	Accuracy
Co-57	1-5	± 5
Ba-133		
Cs-137	.2	± 5

C. x — The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator.
*see comment below

or

___ Equivalent procedures are attached.

*Must be equivalent to the highest activity used.

* The procedures described in Section 2 of Appendix D will be used except that the linearity check will be performed 1/year rather than quarterly.

Information in Support of Xe-133 Use Appendix M (Rev. January 1979)

a. Quantities to be used:

(1) Patient information

(a) 10 studies per week

(b) 10 milliCuries average activity per study

(2) 200 milliCurie possession limit

b. Use and Storage Areas:

(1) Xe-133 will be stored in "Hot" Lab and used (administered, imaged, trapped, and exhausted) in Camera Room (see attached facility diagram).

(2) Ventilation (see attached facility diagram)

(3) In case of fan shutdown, Xe-133 studies will not be performed.

c. Procedures for Routine Use:

(1) Xe-133 will be stored in "Hot" Lab in the lead shipping tubes behind lead bricks. Individual "doses" will be assayed in our "dose" calibrator and administered using the Xenon Xe 133 Gas Calidose Dispensing System (NEN).

(2) Xe-133 will be administered to the patient using the Pulmonex Xenon System (Atomic Products) (see the attached brochure). Xe-133 will be collected using the _____ (see the attached brochure).

(3) Nose clamps will be used to reduce leakage.

d. Emergency Procedures:

Notify persons in the room that a release has occured.
All persons should vacate the room at once.
Close the door to room and prevent entry.
Notify the Radiation Safety Officer immediately.
After 15 minutes* re-enter the room. Survey with G.M. Survey meter to assure that exposure rates have returned to "normal" levels.

* 5 turn-overs of room air

e. Air Concentration of Xe-133 in Restricted Areas:

(1) 10 mCi/patient x 10 patients/week x 1×10^3 uCi/mCi = 1×10^5 uCi/week (A)

(2) Assume a loss rate of 20% (f)

(3) Airflow rate 900 cfm

(4) V (required) = (A x f)/ 1×10^{-5} uCi/ml

$$= \frac{1 \times 10^5 \text{ uCi/week} \times .20}{1 \times 10^{-5} \text{ uCi/ml}} = 2.0 \times 10^9$$

$$\frac{2.0 \times 10^9 \text{ ml/week}}{40 \text{ hr-week}} \div 1.7 \times 10^6 = 30 \text{ cfm}$$

Therefore, 900 cfm is adequate.

f. Methods of Xe-133 Disposal:

Adsorption onto activated charcoal traps

The Xe-133 will disposed of by adsorption and decay onto the Pulmonex xenon-133 gas trap.

Air Concentration of Xe-133 in Unrestricted Areas:

V (required) = (A x f)/ 3×10^{-7} uCi/ml

$$= \frac{1 \times 10^5 \text{ uCi/week} \times .20}{3 \times 10^{-7} \text{ uCi/ml}} = 6.67 \times 10^{10} \text{ ml/week}$$

$$\frac{6.67 \times 10^{10} \text{ ml/week}}{168 \text{ hr-week}} \div 1.7 \times 10^6 \text{ ml/h-cfm} = 233.4 \text{ cfm}$$

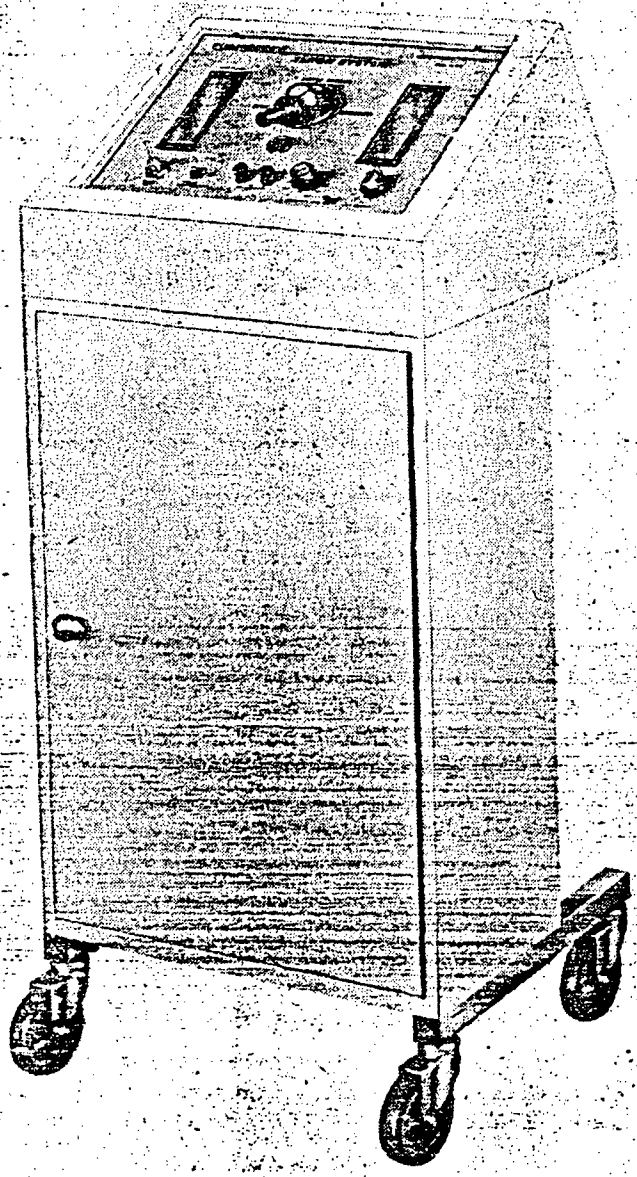
Therefore, 2900* cfm is adequate. *additional dilution from air joining room exhaust

(ii) Effluent from the trap will be collected periodically and counted on the gamma camera (collimator removed) with window set for Xe-133. The trap will be removed from service if the activity exceeds 1×10^5 uCi/ml. (Tested for leakage monthly)

(iii) Saturated filters will be sealed per manufacturer instructions to prevent leakage and will be stored for decay in shielded storage area.

PULMONEX XENON SYSTEM

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



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 observati of patient breathing bags.
- All flow circuits automatically controlled by a master valve system.
- Automatically timed washout.
- Accepts any commercial form of xenc
- Rolls easily on large casters for positioning of supine or seated patients.
- Fully shielded.
- Carbon dioxide and moisture traps included.

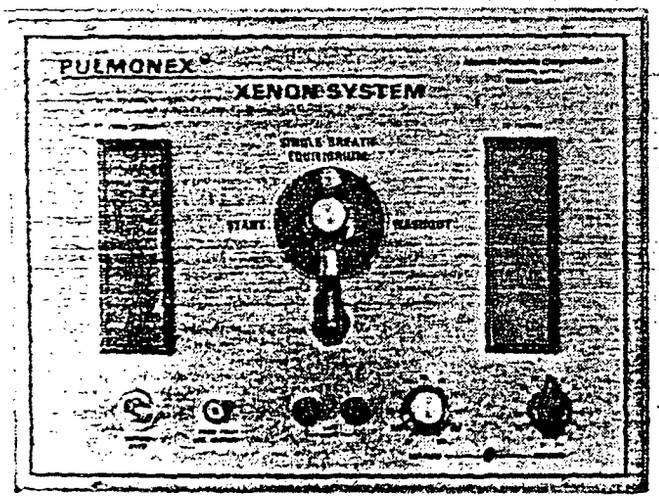
SIMPLE, SAFE OPERATION

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 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_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	$ 2595.00
127-319	Disposable Charcoal Cartridge	$ 295.00
130-550	Disposable Mouthpiece	$ 1.75 ea.
130-700	Disposable Bacteria Filter	$ 2.95 ea.
139-101	Moisture Absorber (Drierite)	$ 6.00 lb.
130-019	Soda Lime, CO_2 Absorber	$ 2.25 lb.

XENON Xe 133 GAS CALIDOSE™

Dispensing System

- Easy and accurate dispensing of unit doses
- Exceptional safety—unique shielding
- Adds specificity to lung imaging

The ventilation-perfusion ratio $\left(\frac{V}{Q}\right)$ is the crucial factor determining the regional oxygen partial pressure. This can be evaluated by assessing the gas exchange occuring in any part of the lung. The single most *sensitive* non-invasive test for diagnosing Pulmonary Embolus is the perfusion lung image.[1] However, pulmonary diseases, such as chronic obstructive lung disease, infectious diseases, and neoplasms are all characterized by altered arterial blood flow. Therefore, the most reliable way to increase the *specificity* of perfusion lung imaging is to add a Xenon 133 ventilation study.[2]

Operation of NEN's Xenon Xe 133 Gas CALIDOSE™ Dispensing System is simple and convenient. After the dispenser is loaded, affix the dispenser to the breathing apparatus with a needle or other connector; push the plunger at the rear of the dispenser (puncturing the septum of the loaded vial by inner needles); and squeeze the rubber bulb.

Caution: Contents to be used *only* for inhalation.

References:

[1] Urokinase Pulmonary Embolism Trial. A National Cooperative Study. *Circulation* (Suppl 11) 47: 11-61. 1973 (April)

[2] Wagner, Henry N. Jr., Strauss, H. William. Radioactive Tracers in the Differential Diagnosis of Pulmonary Embolism. *Progress in Cardiovascular Diseases*, Vol. XVII, No. 4 (January/February), 1975.

ORDERING INFORMATION

NRP-186 Gas CALIDOSE™ Dispenser (Supplied at no charge during the term of an order)

NRP-127 Xenon Xe 133 Gas CALIDOSE refills are available in unit dose vials from 10mCi to 100mCi per vial.

Contact your NEN representative for details concerning Amendment preparation, equipment selection, and purchasing options.

PACKAGE INSERT REPRINT
XENON Xe 133 GAS

July, 1975, Rev. 1

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

ACTIONS: Xenon Xe 133 is a readily diffusable 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.

Control No. 0 3 9 9 3

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 0.44 R/mCi-hr. at 1 cm. The half value layer is 1 mm 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 2 ml 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

Catalog Number NRP-127

VIII Signature of Certifying Official[4]

I hereby certify that this institution (or private practice), is committed to the ALARA Program set forth above.

Barry I. Samuels, M.D.
Signature

Barry I. Samuels, M.D.
Name (print or type)

Director, Nuclear Medicine and Ultrasound
Title

Institution (or Private Practice) Name and Address:

Woodland Medical Group, P.C.
41935 W. Twelve Mile Road
Novi, MI 48050

4) The individual who is authorized to make commitments for the administration of the institution (e.g., hospital administrator, etc.) or, in the case of a private practice, the licensed physician.