

NRC FORM 313M

(9-81)

10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Approved by OMB

3150-0041

Expires 9-30-86

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

West Hudson Hospital
Department of Radiology
206 Bergen Avenue
Kearny, New Jersey 07032
TELEPHONE NO.: AREA CODE (201) 991 - 3400

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

Same as 1.(a)

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Raphael C. Giobbe, M.D.
TELEPHONE NO.: AREA CODE (201) 991 - 3400

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

a. ☐ NEW LICENSE

b. ☐ AMENDMENT TO LICENSE NO. _____

c. ☒ RENEWAL OF LICENSE NO. 29-08532-01

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

Raphael C. Giobbe, M.D.
Thiagarajan Alaguraj, M.D.
Esther Garcia, M.D.
Donald MacPherson, 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.)

Esther Garcia, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	3 mCi each	IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	150 mCi
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	20 mCi
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000 mCi of each	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	150 mCi
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
10 CFR 35.100, SCHEDULE A, GROUP VI					

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
Applicant <u>Mar. 31</u>			
Check No. <u>49524</u>			
Amount/Fee Category <u># 580-7C</u>			
Type of Fee <u>Renewal</u>			
Date Check Rec'd <u>3/3/86</u>			

NRC FORM 313M
(9-81)

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REG1 LIC30
29-08532-01
PDR

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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: _____

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL <i>(Check One)</i>	
☒	Names and Specialties Attached; and	☒	Appendix G Rules Followed; or
☒	Duties as in Appendix B; or _____ <i>(Check One)</i>		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES <i>(Check One)</i>	
8. TRAINING AND EXPERIENCE		☒	Appendix H Procedures Followed; or
	Supplements A & B Attached for Each Individual User; and		Equivalent Procedures Attached
	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES <i>(Check One)</i>	
9. INSTRUMENTATION <i>(Check One)</i>		☒	Appendix I Procedures Followed; or
	Appendix C Form Attached; or		Equivalent Procedures Attached
☒	List by Name and Model Number	18. WASTE DISPOSAL <i>(Check One)</i>	
10. CALIBRATION OF INSTRUMENTS			Appendix J Form Attached; or
☒	Appendix D Procedures Followed for Survey Instruments; or _____ <i>(Check One)</i>		Equivalent Information Attached
	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS <i>(Check One)</i>	
☒	Appendix D Procedures Followed for Dose Calibrator; or _____ <i>(Check One)</i>	☒	Appendix K Procedures Followed; or
	Equivalent Procedures Attached		Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
☒	Description and Diagram Attached		Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or _____ <i>(Check One)</i>
☒	Description of Training Attached		Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
☒	Detailed Information Attached	☒	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL'S <i>(Check One)</i>		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
			Detailed Information Attached
☒	Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached		Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	☐ FILM		
	☒ TLD	Searle Diagnostic	Monthly
	☐ OTHER <i>(Specify)</i>		
b. FINGER	☐ FILM		
	☒ TLD	Searle Diagnostic	Monthly
	☐ OTHER <i>(Specify)</i>		
c. WRIST	☐ FILM		
	☐ TLD		
	☐ OTHER <i>(Specify)</i>		

d. OTHER *(Specify)*

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

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)

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type of Print)*

(2) TITLE

(1) LICENSE FEE CATEGORY:

170.31, 10 CFR 170 Category 7B

c. DATE

February 15, 1986

(2) LICENSE FEE ENCLOSED: \$

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 NRC Form 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.

Item 7 - (cont'd)

February 15, 1986

MEDICAL ISOTOPE COMMITTEE DESCRIPTION

Section 35.11 (b), 10 CFR35 requires the applicant for an institutional NRC license to appoint a Medical Isotope Committee to evaluate all proposals for all uses of radioisotopes within the institution. The Committee approval of this license renewal application is indicated on the "Medical Isotope Committee Statement" cover page to this application.

The function, responsibilities, authority and administrative procedures of this Committee will be as described in the NRC Licensing Guide 10,8 for Medical Programs, dated October, 1980, Appendix B. This institution will meet at least quarterly and record the minutes, which are to be available for inspection at any time.

COMMITTEE MEMBERSHIPLIST

- a. Raphael C. Giobbe, M.D. - Director of Radiology, Chairman - Isotope Committee
- b. Esther Garcia, M.D. - Radiation Safety Officer, Radiology
- c. Thiagarajan Alaguraj, M.D. - Radiology
- d. Dr. Edward I. Holodny - Consulting Physicist
- e. Donald J. MacPherson, M.D. - Pathology
- f. Peter Taddeo, M.D. - Chief, Internal Medicine
- g. Mr. Paul Paracka - Hospital Administration
- h. Satish Madan, M.D. - Chief of Surgery
- i. Barbara Turro - Nursing
- j. Ms. Donna Perlee - Radiology Administrator
- k. Ms. Marylou Petrone - Chief Technologist, Nuclear Medicine

Item 8

February 15, 1986

TRAINING AND EXPERIENCE

- I. Supplements A and B have previously been submitted for each individual user listed in Item #4 of this application. These are the same physicians as previously included in our License.
- II. Supplement A has previously been submitted for our Radiation Safety Officer.

Item 9

February 15, 1986

INSTRUMENTATION

a. Picker Dyna Camera 4/15	Model No. 615236 Serial No. 223537
b. Picker Dyna Camera 4	
c. Dose Calibrator	Capintec CRC - 6A Serial No. 62718
d. Thyroid Uptake Probe	ADC Medical - Model 300
e. Eon Geiger Counter	Model No. 3007 Serial No. 62718
f. Victorean Survey Meter	Model No. 497
g. Victor Survey/Interpretive Meter	Model 407A Panoramic
h. Abbott Gamma Scintillator	for RIA Tests

Item 10

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CALIBRATION PROCEDURES

SURVEY METERS

Survey meters will be calibrated at least annually and after repairs. Calibration will be performed at two points on each scale, as described in NRC Licensing Guide 10.8, October, 1980, Appendix D, Section 1. These calibrations will be performed by Radiation Management Corporation, Philadelphia, Pa., whose radiation sources and procedures are on file with the NRC under License #37-13129-01.

DOSE CALIBRATOR

We shall follow the calibration methods and frequencies for dose calibrators as defined in NRC Licensing Guide, 10.8, October, 1980, Appendix D, Section 2.

For the linearity test, we will use a vial of Tc 99M whose activity is equivalent to the maximum anticipated activity to be assayed.

Item 10 - (cont'd)

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CALIBRATION OF INSTRUMENTSDOSE CALIBRATOR STANDARDS

Cs - 137	Activity - 98 mCi
	Cal. Date - 3/15/77
	Serial No. - 294-228-7
	Accuracy - $\pm$ 5% traceable to NBS
Co - 57	Activity - 5 mCi
	Cal. Date - 1/6/84
	Serial No. - 6083 MA
	Accuracy - $\pm$ 5% traceable to NBS
Co - 60	Activity - 95 mCi
	Cal. Date - 3/15/77
	Serial No. - 294-040-50
	Accuracy - $\pm$ traceable to NBS
Ba - 133	Activity - 279 mCi
	Cal. Date - 9/15/80
	Serial No. - 3580980A-47

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FACILITIES AND EQUIPMENT

The Nuclear Medicine facility consists of the areas diagrammed on the following pages. (Fig. A)

RECEIPT OF RADIOACTIVE MATERIAL

Shipments of radioactive material received during working hours are placed immediately in the hot lab. Any material received after hours is stored in the camera room (which is locked) and transferred to the hot lab at the beginning of the work day.

DOSE PREPARATION AREA

The dose preparation area on the hot lab area work bench, as shown on the facility sketch, is shielded in the front by an upright protective lead barrier (12" x $\frac{1}{2}$ " thick), on top by high density glass and in the rear by standard size lead bricks (2" x 4" x 8"). Disposable gloves, remote handling equipment, lead storage containers and plastic-backed absorbent pads are also used in this hot lab area.

STORAGE AND WASTE AREA SHIELDING

The storage area is located under the lab work bench. It is lead-shielded and is shown on the facility sketch. (Fig.B)

NUCLEAR MEDICINE

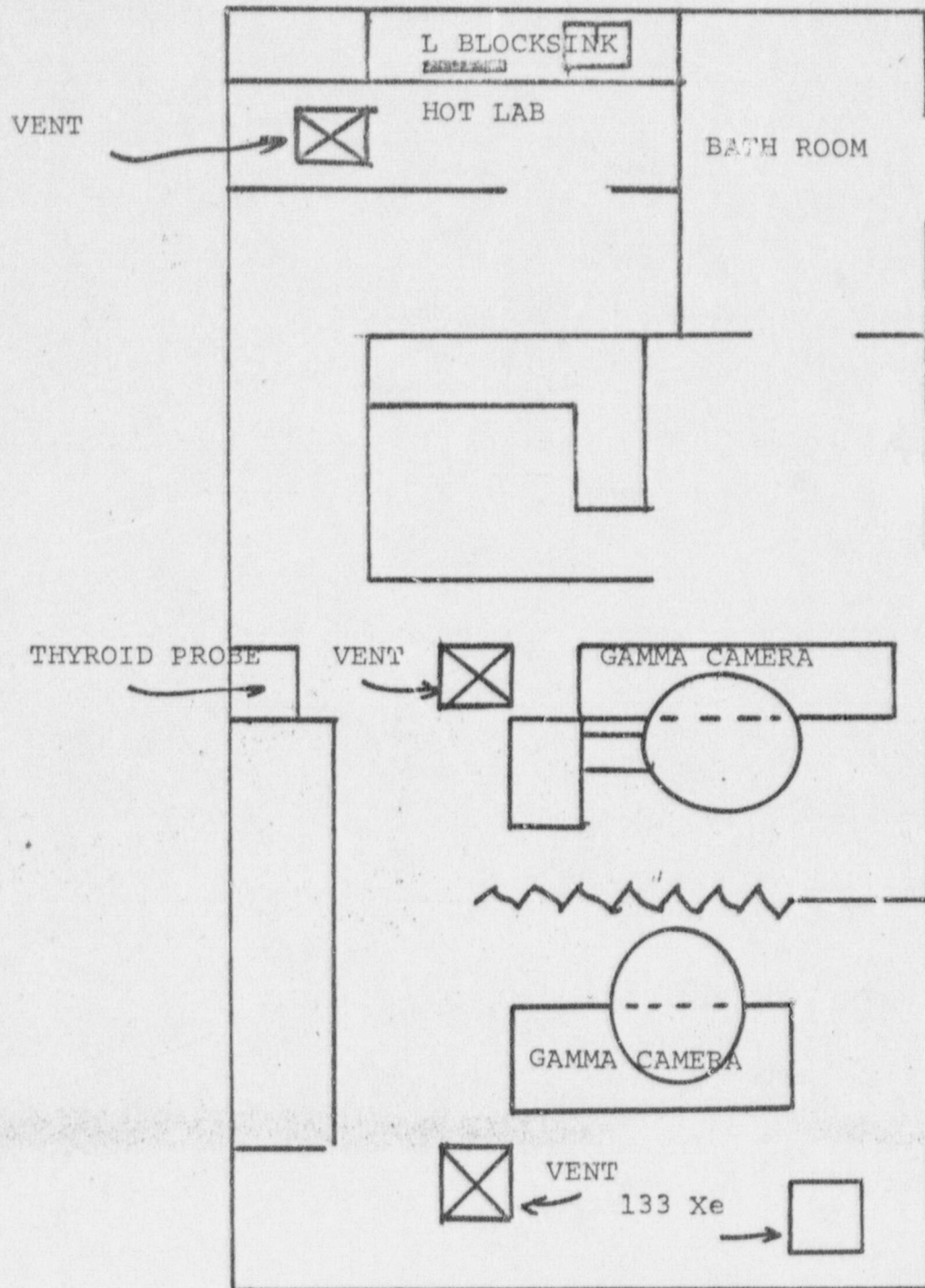


FIG. A

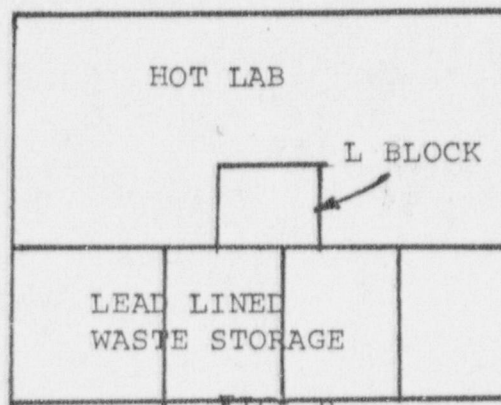


FIG. B

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PERSONNEL TRAINING PROGRAM

I. NUCLEAR MEDICINE PERSONNEL

On a routine basis, the staff of our Nuclear Medicine Department receive continuing education lectures from the staff of our Hospital concerning the science of Nuclear Medicine. They are also encouraged to attend outside lectures and seminars.

In addition, they are given lectures by our health physicist which include the terms and conditions of our Hospital's license, review of parts 19 and 20 of 10 CFR and an update of current safety policy with regards to radiation safety. These lectures are given at the time of hire, at least annually thereafter, or whenever pertinent changes in our program occur.

II. ANCILLARY PERSONNEL

At regular intervals, (i.e. date of hire and at least annually thereafter), all ancillary personnel (i.e. Security Dept., House-keeping Dept., Nursing Staff) who have the occasion to enter a restricted area on a continuing basis or come in contact with persons administered therapeutic quantities of radiopharmaceuticals or packages containing radioactive material, will be given lectures on radiation safety and protection.

These lectures will be documented and available for review by all authorized persons from regulatory agencies. They will include information and material contained in Section 4, Item 12 of NRC Regulatory Guide 10.8, October, 1980.

Item 13

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PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

ORDERING PROCEDURES

Radioactive materials will be ordered by the Chief Nuclear Medicine Technologist on "as needed" basis to maintain inventory at minimal levels. She will insure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

RECEIPT PROCEDURES

During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

During off-duty hours, carriers will be given a key to the locked Nuclear Medicine Department and will be instructed to place the package in the camera room and relock the door. No Hospital personnel will be involved in the receipt of radioactive material during off-duty hours.

The procedures as recommended in Appendix E of Regulatory Guide 10.8 (January, 1979) will be followed in all instances for ordering and receiving radioactive material.

Item 14

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PROCEDURE FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Packages should be opened and inspected immediately upon receipt.

Disposable gloves should be worn while processing the packages and remote handling devices should be used when possible.

1. Visually inspect package for any sign of damage (e.g. wetness, crushed, etc.) If damage is noted, stop procedure and notify Radiation Safety Officer or designata.
2. Measure exposure rate at 3 feet from package surface and record. If greater than 10 mR/hr., stop procedure and notify Radiation Safety Officer or designata.
3. Measure surface exposure rate and record. If greater than 200 mR/hr., stop procedure and notify Radiation Safety Officer or designata.
4. Open the outer package and remove packing slip. Open inner package and verify that the contents agree in name and activity with the packing slip; inspect for breakage of seals or vials, loss of liquid or discoloration of packing material. Check also that shipment does not exceed possession limits.
5. If package appears damaged, wipe external surface of source container with moistened cotton swab or filter paper held with forceps, assay and record. Monitor the packing material and packages for contamination before discarding.

NOTE:

Contaminated containers, liners, shields, etc. should be discarded in the "hot" waste containers. Uncontaminated items may be discarded in the regular waste containers after removing or defacing any radiation labels.

Item 15

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GENERAL RADIATION SAFETY REGULATIONS

It is the responsibility of those working with radioactive materials, to protect themselves and others from radiation hazards arising from their work. Bad example and careless working habits may unnecessarily expose associates or contaminate facilities and cannot be tolerated. The following regulations shall be observed.

1. Radioactive materials may be used only by personnel and for procedures approved by the Medical Isotopes Committee.
2. Radioactive materials will be ordered by the nuclear technologists, under direction of the licensed physician users, on an "as needed" basis to maintain inventory at minimal levels.
3. Disposable gloves and protective clothing should be worn at all times by all personnel when working with radioactive materials. If any garment is contaminated, it shall be placed in a plastic bag and stored behind lead blocks in the hot lab for decay to background levels prior to laundry.
4. Disposable absorbent pads and/or non-porous trays will be utilized in radioactive work areas.
5. Working with radioactive materials when open wounds are present on exposed surfaces of the body is prohibited, unless wounds are properly dressed and protected.
6. Hands, feet and clothing shall be monitored routinely for contamination. Hands should be washed routinely after handling radioactive materials, especially before eating.
7. Perform daily surveys and decontaminate if necessary.
8. Syringe shields shall be used for the preparation and administration of patient doses, except in circumstances, such as pediatric cases, where their use would compromise the patient's well being.
9. Eating, drinking, smoking and the application of cosmetics are prohibited in areas where unsealed radioactive materials are being handled.
10. Pipetting or any similar operation by mouth suction is prohibited.
11. Long-handled forceps and lead shielding should be used when applicable during the preparation of patient doses.
12. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.

Item 15 - (cont'd.)

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13. Appropriate shielding should be used when transporting material from one location to another.
14. Film badges worn at chest or waist level shall be used in controlled areas. Ring badges shall be worn when handling radionuclides. Be sure badges are changed at the appropriate time intervals. Records of radiation exposure shall be available for review by personnel.
15. All radionuclides will be confined in covered containers and properly labeled as to name of compound, radionuclide, date, activity and radiation level if applicable. All radionuclides will be adequately shielded while in use and in storage. All areas where radionuclides are used will be properly posted.
16. Contaminated waste shall be disposed of in the containers provided. Liquid waste should be poured on an absorbent material and disposed of in the containers provided. Contaminated liquid waste shall not be poured into drains without approval of the Radiation Safety Officer.
17. "Good Housekeeping" shall be maintained at all times. Spillage should be prevented, but in the event of such an accident, the prescribed emergency procedures should be followed.

Item 16

February 15, 1986

RADIATION PROTECTION OFFICERADIATION EMERGENCY PROCEDURES MANUAL

In the event of the escape of a radioactive substance from its normal confines, (spill, evaporation, vaporization, combustion, escape of gas, liquid, solid, etc.) take the following steps:

A. AIRBORNE CONTAMINATION

Where airborne contamination (from evaporation, vaporization, combustion, formation of a smoke, dust, spray, escape of gas, etc.) may have occurred:

1. Notify all other persons to vacate the laboratory immediately.
2. Hold breath and turn off all air circulation systems (fans, blowers, air conditioners, etc.) if time permits, to prevent the spread of contamination.
3. Vacate the laboratory.
4. Shut all doors giving access to the laboratory.
5. Post conspicuous warnings or guards to prevent accidental opening of the doors and to insure that no one re-enters the laboratory.
6. Notify the Radiation Safety Officer.
7. Assemble all persons who were in the laboratory at the time of the incident. The place of assembly should be near the contaminated area, in order to reduce the spread of contamination about the building.
8. Report at once, all known or suspected inhalations of radioactive materials.
9. Monitor assembled personnel if an instrument is available, to determine whether contamination of the skin or clothing exists. If such contamination is found, proceed as follows:
 - a. Remove all contaminated clothing.
 - b. Wash contaminated areas of skin with soap and water. Do not scratch skin surface.
10. Do not attempt immediate decontamination of the area unless the situation threatens to become worse. With the Radiation Safety Officer, devise a safe plan for re-entry and clean-up.
11. File a "Radiation Incident Report", giving a complete history of the accident and related subsequent activities.

Item 16 - (cont'd.)

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B. SPILLS

Where there is a spill of radioactive material that will not readily become airborne (such as a solid, not so finely divided that it may be carried about as a dust, or a liquid of relatively low volatility, such as an aqueous solution, provided spraying did not occur):

1. Notify all persons not involved in the spill to vacate the laboratory at once.
2. Flush skin thoroughly with running water, if the spill is on the skin.
3. Remove all contaminated clothing at once, if the spill is on the clothing.
4. Confine the spill.

a. Liquid Spills:

Don protective gloves.
Dampen thoroughly, taking care not to spread the contamination.

5. Turn off all air circulating systems.
6. Vacate the laboratory.
7. Shut all doors giving access to the laboratory.
8. Post conspicuous warnings or guards to insure that no one enters the laboratory.
9. Notify the Radiation Safety Officer as soon as possible.
10. Assemble all persons who were near the site of the spill. The place of assembly should be near the contaminated area in order to reduce the spread of contamination about the building.
11. Monitor the skin and clothing of all persons, if an instrument is available. If contamination is found, proceed as follows:
 - a. Remove all contaminated clothing.
 - b. Wash contaminated areas of skin with soap and water. Do not scratch skin surface.
12. Decontaminate area.
13. File a "Radiation Incident Report", giving a complete history of the accident and related subsequent activities.

C. INGESTION

Where ingestion of radioactive material may have occurred:

1. Induce vomiting by placing a finger well back in the throat.
2. Have victim drink a pint of water and induce vomiting again. Repeat until vomitus is clear.
3. Notify the Radiation Safety officer at once.

Item 16 - (cont'd.)

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4. File a "Radiation Incident Report", giving a complete history of the accident and related subsequent activities.

No person involved in a radiation injury shall be permitted to return to work without the approval of the Radiation Safety Officer and the attending Physician.

E. FIRE OR OTHER MAJOR EMERGENCIES

In the event of a fire, flooding or other major emergencies, inform the fire department or other emergency personnel responding to the emergency call of the potential radiation hazard. Notify the Radiation Safety Officer as soon as possible. Govern the fire fighting or other emergency activities by the restrictions of the Radiation Safety Officer.

Item 17

February 15, 1986

SURVEY PROCEDURES

There are three basic types of routine surveys done in the Nuclear Medicine spaces; namely, daily surveys of the dose preparation and injection areas, weekly surveys of the entire hot lab, camera room and scan room and monthly surveys of the in-vitro laboratory.

The weekly and monthly surveys consist of wipe tests and exposure surveys. Exposure surveys are done with a beta-gamma G-M survey meter sensitive to 0.1 mR/hr. Wipe tests consist of cotton swab wipes that are counted in a detector sensitive to 100 dpm.

For exposure surveys, the exposure rate is not allowed to exceed 1 mR/hr. In actual practice, the readings are usually less than 0.1 mR/hr. Should readings exceed allowed limits, additional shielding is provided.

For wipe tests, areas with more than 100 dpm must be decontaminated. Should higher levels persist after decontamination, shielding or isolation is attempted as deemed necessary.

Survey records of the hot lab, camera and scan room are maintained in our survey log book. Information recorded includes location, date and type of equipment used, name of surveyor, drawing of area surveyed, measured exposure rates and contamination levels-keyed to locations on drawing, corrective action taken and reduced contamination levels and exposure rates after corrective action.

Item 18

February 15, 1986

WASTE DISPOSAL

1. Liquid waste from RIA procedures will be disposed of into 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 waste material: Due to the current stringent regulations, we at West Hudson Hospital would like to dispose of waste materials not listed above, by either:
 - A. All isotopes are decayed to at least ten (10) half-lives, then monitored and if the exposure rate is background or less, after removing labels, disposed into hospital waste. A record is kept.
 - B. Disposed of by a commercial waste disposal firm.

We wish the ability to choose which method is best suited for our institution and to switch between the two as we see fit in accordance to conditions and requirements imposed by the operating burial sites.

Item 19

February 15, 1986

PROCEDURES FOR TREATMENT OF PATIENTS WITH IODINE 131

1. All patients treated with Iodine 131 will be placed in a private room with a toilet.
2. The patient's room will be properly posted.
3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, three feet away, and the entrance to the room. The Radiation Safety Officer or his designate, will then determine how long a person may remain at these positions and will post these times in the patient's chart and on his door. The results of daily surveys will be used to re-calculate permitted times which will be posted on the patient's chart and his door.
4. The form, Nursing Instructions for Patients Treated with Iodine 131, will be completed immediately after administration of the treatment dose. A copy will be posted in the patient's chart.
5. Radiation levels in unrestricted areas will be maintained less than the limits specified by the NRC Code.
6. All linens will be surveyed for contamination before being removed from the patient's room and will, if necessary, be held for decay.
7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer (or his designate), checked for contamination, and disposed of as normal or radioactive waste, as appropriate.
8. Non-disposable items used for these patients will be held in plastic bags in the patient's room and checked for contamination by the Radiation Safety Officer (or his designate). Items may be returned for normal use, held for decay, or decontaminated, as appropriate.
9. Urine and vomitus, from Iodine-131 therapy patients will be stored for decay in the radioactive waste storage area. When it has reached background levels as measured with a low-level survey meter, it will be released to the sanitary sewer system.
10. Before a therapy patient's room is re-assigned to another patient, the room will be surveyed for contamination (and decontaminated if necessary) and all radioactive waste and waste containers will be removed.
11. NURSING INSTRUCTIONS:
 - a. Nurses should spend only that amount of time near the patient, required for ordinary nursing care. Special restrictions may be noted on the precaution sheet in the patient's chart. Nurses should read these instructions before administering to the patients. Call the Radiation Safety Officer if you have any questions about the care of these patients.

Item 19 - (cont'd.)

February 15, 1986

- b. Visitors will be limited to those 18 years of age and over, unless other instructions are noted on the precautions sheet in the patient's chart.
 - c. Patients must remain in bed while visitors are in the room, and visitors should remain at least three feet from the patient.
 - d. Radioactive patients are to be confined to their rooms except for special medical or nursing purposes approved by the Radiation Safety Officer.
 - e. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.
 - f. Attending personnel must wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves must be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.
- 8.
- 1. Urine from Iodine-131 patient will be collected in special containers provided by the Radiation Safety Office. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bedpan should be flushed several times with hot soapy water after use.
 - 2. If the nurse helps to collect the excreta, she should wear disposable gloves. Afterwards, she should wash her hands with the gloves on and again after the gloves are removed. The gloves should be placed in the designated wastecontainer for disposal by the Nuclear Medicine Department.
 - 3. Disposable plates, cups and eating utensils will be used by patients who are treated with Iodine-131.
 - 4. Vomiting within 24-hours after oral administration, urinary incontinence, or excessive sweating within the first 48-hours may result in contamination of linen and/or floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer, Ext. 7066, 7055 or 7073. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.
 - 5. All vomitus must also be kept in the patient's room for disposal by the Nuclear Medicine Department. Feces need not be routinely saved unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed, three times.

Item 19 - (cont'd.)

February 15, 1986

- h. Utmost precautions must be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer.
- i. If a nurse, attendant or anyone else knows or suspects that his skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer immediately. This person should remain in the patient's room and not walk about the Hospital. If the hands become contaminated, wash immediately with soap and water.
- j. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer immediately.
- k. When the patient is discharged, call the Radiation Safety Officer and request that the room be surveyed for contamination before re-making the room.

Item 19

Date: _____

NURSING INSTRUCTIONS FOR PATIENTSTREATED WITH IODINE-131

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotopes Administered: _____

Date and Time of Administration: _____ Method of Administration _____

EXPOSURE RATES IN mR/hr.

Date _____ 3 feet from bed _____ 10 feet from bed _____

(Comply With All Check Items)

- _____ 1. Visiting time permitted: _____
- _____ 2. Visitors must remain _____ from patient.
- _____ 3. Patient may NOT leave room.
- _____ 4. Visitors under 18 NOT permitted.
- _____ 5. Pregnant visitors NOT permitted.
- _____ 6. TLD film badges must be worn.
- _____ 7. Use and complete the following tags:

_____ door

_____ bed

_____ chart

_____ wrist

Item 19 - (cont'd.)

- _____ 8. Gloves must be worn while attending patient.
- _____ 9. Patient must use disposable utensils.
- _____ 10. All items must remain in the room until okayed by Radiation Safety.
- _____ 11. Smoking is NOT permitted.
- _____ 12. Do not release room to admitting until okayed by Radiation Safety.
- _____ 13. Other instructions,

IN CASE OF AN EMERGENCY, CONTACT:

RSO _____	/	_____
Name	ON/OFF DUTY	Telephone Number

Item 21

February 15, 1986

USE OF XENON 133A. QUANTITIES TO BE USED

During the past year, approximately 5 Xenon-133 studies were performed. The average activity per patient was 10 millicuries. The desired possession limit is 30 millicuries.

B. USE AND STORAGE AREAS

The Xenon-133 will be stored in the hot lab (see diagram shielded by standard size lead bricks (each 2" thick x 4" wide x 8" long) and used in the Camera Room (see diagram). The doors to the Camera Room are closed during Xenon studies.

As indicated, a ceiling exhaust vent I with a measuring air flow rate of 286 CFM and a ceiling exhaust vent II is also of 286 CFM. None of this air is re-circulated by the system.

C. PROCEDURES FOR ROUTINE USE

The Xe-133 ventilation study system we are using is a complete disposable system. It consists of Xe-133, a CO₂ absorber canister, a breathing-collection bag and a disposable mouthpiece. The procedures we follow for routine use of Xe-133 is found in the attached brochure. A Xenon-133 gas trap "Pulmonex", manufactured by Nuclear Associates, Inc. will be used to remove the exhaled Xe-133.

D. EMERGENCY PROCEDURES

In the event of an accidental release of Xenon-133, all patients and personnel would be immediately evacuated from the area and this area would be sealed off and the Radiation Safety Officer notified.

Assuming that the maximum amount of Xenon-133 gas was released into the air, that would mean that 10 millicuries would be released into a volume of 2880 cubic feet. The initial concentration of Xenon gas would therefore be:

$$\frac{10,000 \text{ uCi}}{2880 \text{ cu.ft.} \times 28320 \text{ ml/cu.ft.}} = 1.23 \times 10^{-4} \text{ uCi/ml}$$

Since the ventilation system within this area operates at a rate of 572 CFM, the concentration of the Xenon within the air of the area will be reduced to the maximum permissible concentration of Xenon within a restricted area of 1×10^{-5} uCi/ml after 62 minutes.

$$\frac{10,000 \text{ uCi}}{1 \times 10^{-5} \text{ uCi/ml} \times 572 \text{ cu.ft./min.} \times 28320 \text{ ml/cu.ft.}} = 62 \text{ min.}$$

Item 21 - (cont'd.)

February 15, 1986

E. AIR CONCENTRATIONS OF XENON-133 IN RESTRICTED AREAS

As stated earlier, approximately 5 Xenon-133 ventilation studies were performed last year. However, since we are requesting a maximum possession limit of 30 mCi, all calculations will be based on the assumption of 30 mCi of activity to be used per week. This represents more than a factor of 30 increase over our actually anticipated case load. A 20% leakage rate from the use of Xenon-133 is assumed.

Required ventilation rate is:

$$A = \frac{10^4 \text{ uCi}}{\text{patient}} \times \frac{3 \text{ patients}}{\text{week}} = 3 \times 10^4 \frac{\text{uCi}}{\text{week}}$$

$$V = \frac{3 \times 10^4 \frac{\text{uCi}}{\text{week}} \times .20 \text{ (lose rate)}}{1 \times 10^{-5} \text{ uCi/ml}} = 6 \times 10^8 \frac{\text{ml}}{\text{week}}$$

$$\frac{6 \times 10^8 \text{ ml/week}}{40 \text{ hrs/week} \times 1.7 \times 10^6 \text{ ml/hr/CFM}} = 9 \text{ CFM}$$

The ventilation rate in our Camera Room is 572 CFM with no recirculation of air.

F. METHOD OF XENON-133 DISPOSAL

Our method of Xenon-133 disposal is by absorption onto a charcoal trap - "Pulmonex", manufactured by Nuclear Associates, Inc., (brochure attached). The following calculations show that even with an assumed 20% leakage rate, the concentration of Xe-133 in unrestricted areas will not exceed 3×10^{-7} uCi/ml.

At point of release from ceiling vent on roof.

$$A = \frac{3 \text{ patients}}{\text{week}} \times \frac{10^4 \text{ uCi}}{\text{patient}} \times .20 \times 52 \frac{\text{weeks}}{\text{year}} = 3.12 \times 10^5 \text{ uCi/year}$$

$$V = 572 \text{ CFM} \times 1.48 \times 10^{10} \frac{\text{ml/yr.}}{\text{CFM}} = 8.47 \times 10^{12} \text{ ml/year}$$

$$C = \frac{3.12 \times 10^5 \text{ uCi/year}}{8.47 \times 10^{12} \text{ ml/year}} = 3.7 \times 10^{-8} \text{ uCi/ml}$$

Item 21 - (cont'd.)

February 15, 1986

- (ii) To insure that collection and trapping devices are performing according to specifications, the system will be monitored with a Geiger Counter during each study. With a Geiger Counter placed at the end of the trap system, the air emerging should indicate very low or no Xenon activity. If the activity of Xenon increased during this test, it will indicate the charcoal cartridge is saturated and a new cartridge will be installed.
- (iii) The saturated filter will be placed in an air-tight container and placed in the radiation waste area in the hot lab, to decay. It will be surrounded by sufficient lead shielding to reduce the radiation levels to background.

Leakage of Xe-133 in the hot lab storage area will be contributed by the sealed plastic tube containing Xe-133 (0.01% leakage per day as stated by manufacturer) and the used plastic bag assemblies with residual Xe-133 (approximately 25 uCi/bag) left for decay. The following calculation shows that the measured air flow rate of 286 CFM from the ceiling exhaust in the hot lab is sufficient to maintain the concentration below the 1×10^{-5} uCi/ml for restricted areas.

Sealed plastic tube

$$A = \frac{30 \text{ mCi}}{\text{week}} \times 0.01\% \times \frac{5 \text{ days}}{\text{week}} = 15 \text{ uCi/week}$$

Used plastic bag assembly

$$25 \text{ uCi/bag} \times 3 \text{ bag/week} = 75 \text{ uCi/week}$$

$$\text{Total activity} = 100 \text{ uCi/week}$$

$$V = 286 \text{ CFM} \times 1.7 \times 10^6 \frac{\text{ml/hr}}{\text{CFM}} \times \frac{40 \text{ hours}}{\text{week}}$$

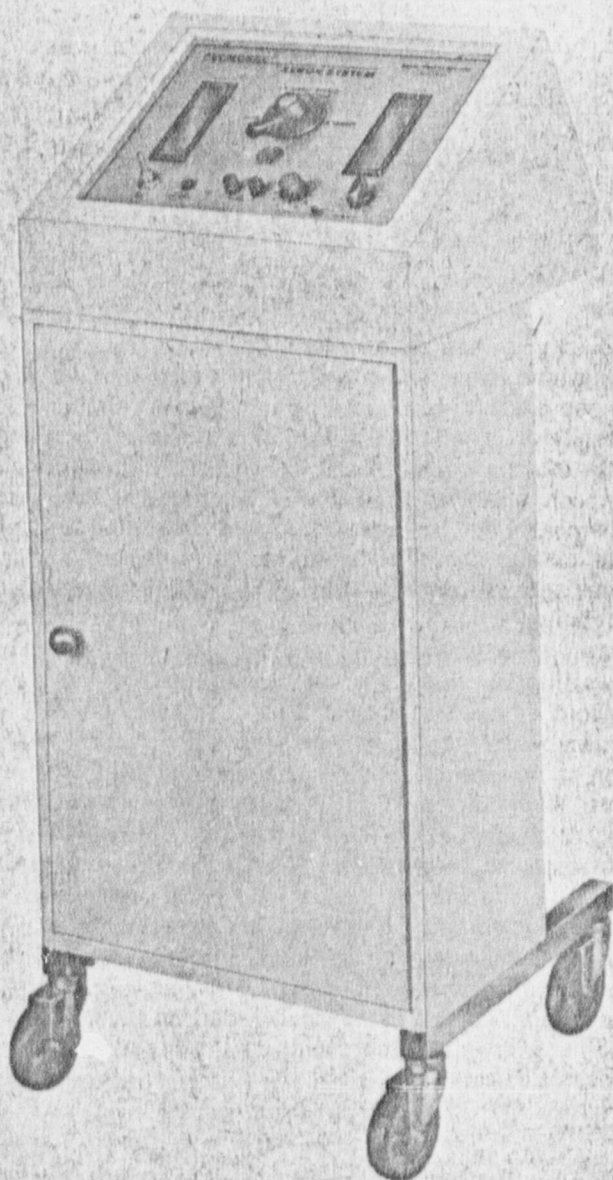
$$2 \times 10^{10} \text{ ml/week}$$

$$C = \frac{A}{V} = \frac{100 \text{ uCi/week}}{2 \times 10^{10} \text{ ml/week}} = 5 \times 10^{-9} \text{ uCi/ml}$$

All personnel in the Department of Nuclear Medicine will receive instruction in the safe routine handling, emergency handling and disposal of this Xenon system.

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 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.

SIMPLE, SAFE OPERATION

XENON DELIVERY UNIT



PERFORMS ALL
REGIONAL
VENTILATION
STUDIES

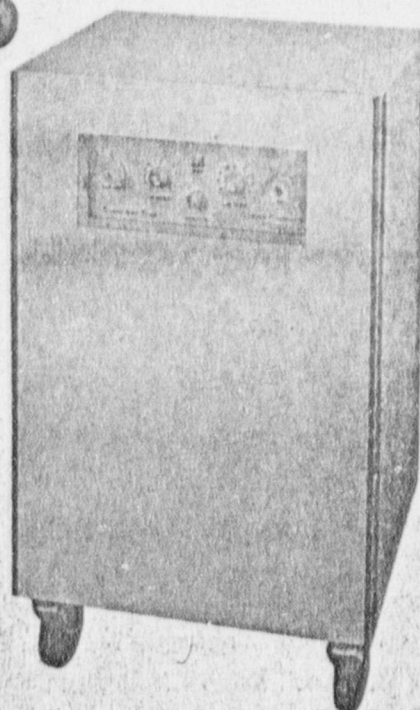
#130-330

The Model 137-133 Xenon Delivery Unit offers an uncomplicated and inexpensive method for delivering Xenon gas for regional ventilation studies. Designed for simple, efficient and reliable operation, the unit will perform rebreathing, washout, perfusion and single breath studies with a minimum of effort. Two valves mounted on the instrument panel direct air flow for the procedure desired.

A lead glass viewing window in the panel permits observation of the breathing bag. Oxygen is thus monitored at the initiation of the study and added if required during the procedure. A push button valve starts and stops the O_2 flow. A one-way valve allows resistance free breathing in equilibrium and washout cycle. Simple-to-follow panel instructions and full lead lining insure complete safety for patient and technician.

The unit will accept any commercially available Xenon source. The washout exit port can be easily vented to a trap, bag or hood. A CO_2 absorber cartridge is placed in line to prevent CO_2 build-up within the closed circuit. The cartridge is easily replaced between patient studies. A bacteria trap eliminates the need for sterilization. Each system includes complete instruction manual. Size 18" x 19" x 39".

XENON GAS TRAP



REMOVES XENON
FROM
EXHALED AIR

YEAR
GUARANTEE
ON
CARTRIDGE

#127-313

Now Xenon can be efficiently removed from exhaled air without the awkwardness and expense of venting to the outside. Such venting is regulated and may be completely prohibited by NRC or state law. The Atom-lab 127-313 lead shielded Xenon Gas Trap draws air through a bed of specifically compounded activated charcoal aggregate. As expelled air migrates through the cartridge, radioactive xenon adheres to the charcoal aggregate and eventually decays. The cartridge is designed, packed and mounted to give optimal adsorption efficiency and prevent "channelling" and "walling" of the gas. The trap effluent is virtually devoid of radioactivity. The patient output is gently drawn in by an induction vacuum pump; flow speed can be adjusted and monitored to assure patient comfort. A timing device allows the operator to choose the desired washout time (1 to 15 minutes) and automatically shut down when the study is completed. A pilot light indicates when the unit is in operation.

The model 127-313 Xenon Gas Trap can be easily integrated into any ^{133}Xe system or may be used independently as a patient exhalation unit. The 1/8" lead shielding makes external radiation levels negligible. A dessicant cartridge on the input line functions as a water trap.

SPECIFICATIONS

Size: 18" x 19" x 34"
Mobility: Rolls on 4" casters
Weight: 125 Lbs.
Finish: White-Formica

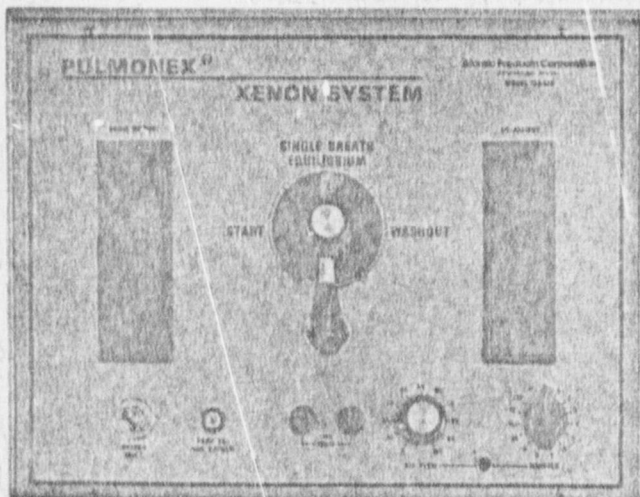
Power: 115V.
Controls: On-Off/Timer
switch, Pilot Light,
Air Flow Controls

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 CO₂ 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.

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration -

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

03002514
~~021/20~~
4/86

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED

Applicant/Licensee:

West Hudson Hospital

Application Dated:

2-15-86

Control No.:

105110

License No.:

29-08532-01

2. FEE ATTACHED

Amount:

\$580.

Check No.:

49524

3. COMMENTS

Signed

eyr

Date

2/27/86

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount:

7c

(\$580)

2. Correct Fee Paid. Application may be processed for:

Amendment

Renewal

✓

License

Signed

J. Jackson

Date

3/4/86