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

Washington Hospital Center
110 Irving St. N.W.
Washington, D.C. 20010

TELEPHONE NO.: AREA CODE (202) 541-0500

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

Kenneth D. Williams

TELEPHONE NO.: AREA CODE (202) 541-6496

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 08-03604-03

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

Individuals approved by the Radiation Safety Committee

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.)*

Kenneth D. Williams

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		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
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		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRA-CAVITARY 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.		

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
SEE SUPPLEMENTAL SHEETS			

8008200293

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 *(Check One)*	
X	Names and Specialties Attached; and	X	Appendix G Rules Followed; or
X	Duties as in Appendix B; or *(Check One)*		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE		X	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 *(Check One)*	
9. INSTRUMENTATION *(Check One)*		X	Appendix I Procedures Followed; or
	Appendix C Form Attached; or		Equivalent Procedures Attached
X	List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*	
10. CALIBRATION OF INSTRUMENTS		X	Appendix J Form Attached; or
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*		Equivalent Information Attached
	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached		Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
X	Description and Diagram Attached	X	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM		X	Appendix L Procedures Followed; or *(Check One)*
X	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)	
X	Detailed Information Attached	X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
		X	Detailed Information Attached
X	Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached	X	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

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)* Richard M Loughery

(1) NAME *(Type or Print)* Richard M Loughery

(1) LICENSE FEE CATEGORY: Medical Licence Renewal

(2) TITLE Chief Executive Officer

(2) LICENSE FEE ENCLOSED: $ 150.00

c. DATE

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6 b.

Byproduct Material (element and mass number)	Chemical and/or physical form	Maximum amount of radioactivity which licensee may possess at any one time
A. Any byproduct material between Atomic Nos. 3 and 83, inclusive	A. Any	A. 100 millicuries of each byproduct material between Atomic Nos. 3 and 83, inclusive
B. Iodine 125	B. Any	B. 500 millicuries
C. Iodine 131	C. Any	C. 1 curie
D. Phosphorus 32	D. Any	D. 500 millicuries
E. Xenon	E. Any	E. 1.5 curie
F. Molybdenum 99	F. Molybdenum 99/ Technetium 99M generators	F. 5 curies
G. Technetium 99m	G. Any	G. 5 curies
H. Cesium 137	H. Sealed Sources	H. 2 curies
I. Hydrogen 3	I. Any	I. 200 millicuries
J. Iridium 192	J. Any	J. 400 millicuries

Total possession limit for A through J. 18 curies

Purpose of use: Medical Research, Diagnosis and Therapy

7 (a) Radiation Safety Committee Membership

Nicholas Nolan, M.D.	Chairman (per letter 7-31-81)
Edwin Hand	Radiopharmaceutical Consultant
~~Eduard Kotlyarov, M.D.~~	Nuclear Medicine
Vernon Martens, M.D.	Pathology
Domenic Sabatini, M.D.	Radiological Physics
Stanley Schwartz, M.D.	Medicine
Kenneth Williams, M.S.	Radiological Physics
Douglas Shepherd	Office of Medical Director
Trueman Haskell	Assist. Admin.-Risk Management

Dr. Kotlyarov (see attachment # 1 for CV) has not been previously approved by the Commission. He was certified by the American Board of Nuclear Medicine in 1976. Messrs Shepherd and Haskell are from hospital administrative management.

The President of the WHC Medical and Dental Staff, Dr. F. Norman Berry , has selected Dr. E. Kotylarov to replace Dr. Jose Baselga as chairman of the Committee beginning September 1, 1980 (Dr. Baselga is leaving the hospital).

(b) 1. The Radiation Safety Committee is established as the administrative body responsible for the safe use of radiation sources within the Washington Hospital Center. The membership and chairman shall be appointed by the President of the Medical and Dental Staff.

The duties of the committee will be as outlined in Appendix B to Regulatory Guide 10.8.

2. The Committee will meet as often as necessary to conduct its business but not less than once in each calendar quarter . A quorum shall consist of the Chairman, RSO and one other member from pathology, radiology or Nuclear Medicine.

3. The Committee will evaluate each new proposed user's application for use of radioactive material on the bases of information obtained on Forms RSO-1 (Training and Experience) and RSO-2 (Laboratory Facilities for Handling Radioactive Materials). Additional information may be required depending on the type of application (see attachment # 2 which is reprinted from our Radiation Safety Manual). The Committee or one of its members will inspect the facilities and equipment prior to approving the application.

As a minimum for training and experience the Committee will use the criteria specified in Appendix A to Regulatory Guide 10.8 for reviewing and approving physicians using radionuclides in humans.

7 (b) 3. (con't.)

The criteria for evaluation of the operating and handling procedures will be based on Appendices F,G,I and J to regulatory Guide 10.8. Periodic inspections by the Committee will be made to verify compliance. The Committee will also periodically evaluate the activities and functions of the Radiation Safety Office. Emergency Procedures will be evaluated on the basis of Appendix H to Regulatory Guide 10.8 by asking individuals what they would do in case of a major spill.

4. The Chief Nuclear Medicine Technologist will place all orders for radioactive materials and ensure that the requested materials are authorized by the Radiation Safety Committee and that the possession limits are not exceeded.

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

   During off hours, security personnel will accept delivery of radioactive materials and deliver them to the Nuclear Medicine Department with instructions simular to those in Appendix E of Regulatory Guide 10.8.

   The Nuclear Medicine Department Computer is being programmed for maintaining inventories, individual possession limits and total possession limits. It is anticipated that patient doses, waste disposal and transfer of radioactive materials will also be included in the program.

   Periodic inspections by the Committee will be made to each laboratory ot assure that each user is in compliance with the conditions of this license.

5. The minutes of each Committee meeting are distributed to each member of the Committee. In addition a copy is sent to the Chief Executive Officer, the President of the Medical and Dental Staff and a copy is filed in the Radiation Safety Office.

   The evaluations of proposed users and inspection results are on file in the Radiation Safety Office.

6. The Radiation Safety Committee will conduct an annual review of the Hospital's Radiation Safety Program.

8. (a) 1. For physicians requesting radioactive material for human use, the criteria specified in Appendix A of Regulatory Guide 10.8 dated January 1979 will be followed.

2. For physicians and other individuals using radioactive material for non human use the Committee will require individuals to meet the criteria specified in section 33.15 of 10 CFR 22.

(b) The Radiation Safety Officer, Mr. Kenneth D. Williams has previously been approved by the Committee.

9. (a) Survey and Monitoring Instrements

1. Victoreen Model 440 portable Survey Meter. Response to gamma radiation over the range 30 keV to 1.3 MeV. Radiation levels detectable to 0.3 mR/hr. Ion chamber type with ranges of 0-3, 0-10,0-30,0-100,0-300 mR/hr.

2. Victoreen Model 570 condensor R-meter with Model 621 chamber. Effective energy range 250 keV to 1.3 MeV. The chamber range is 100 R.

3. Victoreen Model 555 Radcon II with Model 555-10HA and 555-100HA probes. Energy range for both probes 200 keV to 1.3 meV. Sensitivity range 30 mR/m to 100 R/m and 300 mR/m to 1000 R/m respectively.

4. Capintec Model 192 Exposure/Exposure rate meter with Model PR-06C chamber. Energy range 100 keV to 1.3 MeV with a sensitivity of 0.200 nC/R. The maximum display is 2000 R or R/M.

5. Nuclear Associates, Inc. PRIMALERT 10. The detector is an energy-compensated GM tube. Energy range 60 keV to 2 MeV. Selectable alarm level of either 2.5 or 28 mR/hr. Visual alarm consists of 2 bright red flashing on-off lamps. 180° field of view.

6. Victoreen Model 493 GM Survey Meter with 498-35 probe. Scale ranges are 0-0.5, 0-5 and 0-5 mh/hr.

9. (b) The typical authorized use will have a GM survey meter (Similar to Victoreen Model 493) for area monitoring and hand and feet monitoring.

10. (a) Survey Instruments will be calibrated by:
Radiation Service Organization
P O Box 419
5204 Minnick Rd
Laurel, Md. 20810

Their license is Md-33-021-01 and their calibration information has been filed with the Commission.

10. (b) Dose calibrator will be calibrated in accordance with Appendix D of regulatory Guide 10.8.

When the service is available the dose calibrator may be calibrated by Radiation Service Organization.

11. Facilities and Equipment
Refer to attachment # 3 for figure references.

The main nuclear medicine department, where 98% of the byproduct material is used, is located in the West addition G Unit basement of the hospital. It is out of the mainstream of patient and visitor traffic.

The following equipment is located in the Nuclear Medicine area. (Figure 2)

ROOM	EQUIPMENT
BG-5	Blos Nuclear Stethoscope
BG-11	Squibb Radioisotope Calibrator CRC 6A Baird Atomic Ratemeter 441A Victoreen 490 # 3702
BG-17	GE Maxi Camera II Radx Ventil-con Xe-133 system
XY	Searle Analytic Camma System # 1197
AB	Picker Spectro Scaler 4R
BG-12	Picker Magna Scanner Ohio Nuclear Dual Scanner
BG-16	GE Data Camera
BG-20	GE Maxi Camera II
BG-18	Ohio Nuclear Radioisotope Camera

The dose preparation laboratory is shown in more detail in Figure 3. All preparations, except I-131 therapy, are done in this room. All radionuclides are stored in the two lead lined caves, except for the Mo-99/Tc-99m generators which are eluted and stored in Room BB 44 (Figure 4).

The RIA counting room BB-24 is located in the basement, Unit B, between the D and F UNITS (Figure 1). A detailed drawing, Figure 5, shows the location of the fume hood and equipment.

11. The Pathology RIA laboratory is located on the ground floor at the south west corner of the E unit (Figure 1). A detailed drawing, Figure6, shows the location of the equipment.

The Anesthesiology laboratory is located on the fourth floor, north end of the east addition (Figure 1). Figure 7 shows the location of the equipment.

Radium and Cesium-137 brachytherapy sources are stored in two locations in the hospital. Room BA-94 is located in the basement of the east addition and Room G is located on the ground floor to the south of the east addition (Figure 1). Figure 8 shows the location of the safes and shielding for sources used rountinely. Figures 9 and 10 show the location of another safe used to store sources that are rarely used. Both rooms have safes with locks and special locks are provided for the doors.

12. Personnel Training Program

In accordance with NRC IE Bulletin No.79-19 dated August 10, 1979 training and periodic retraining in DOT and NRC regulatory requirements will be incorporated as part of the weekly one hour training sessions currently provided by the Nuclear Medicine Department for their personnel. Persons designated from other departments will be asked to attend these sessions. It is anticipated that the periodic retraining sessions will occur twice yearly. All new employees who generate radioactive waste will receive such training upon employment.

All individuals whose duties may require them to work in the vicinity of radioactive material will be instructed as required by section 19.12 of 10CFR19.

13. Procedures for ordering and receiving radioactive material are based on those specified in Appendix E of Regulatory Guide 10.8.

(a) The Chief Nuclear Medicine Technologist will place all orders for radioactive material and will ensure that the required materials and quantities are authorized by the Radiation Safety Committee and that the possession limits are not exceeded .

During normal working hours, carriers will be instructed to deliver materials direct to the Nuclear Medicine Department.

During off duty hours, security personnel will be instructed to accept delivery of radioactive materials and deliver them to the Nuclear Medicine Department.

13. (a) (con't)

SAMPLE MEMORANDUM

TO: Protective Services

FROM: Chief Executive Officer

Subject: Receipt of Packages containing Radioactive Material

Any packages containing radioactive material that arrives between 4:30 pm and 7:00 am or on weekends or holidays shall be signed for by the Security Guard on duty and taken immediately to the Nuclear Medicine Department, Room BB 44. Unlock the door, place the package on the floor inside of the room, and relock the door.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

Radiation Safety Officer: Kenneth D. Williams
Office Phone : 541-6496

14. The procedures outlined in Appendix F of Regulatory Guide 10.8 will be followed for safety opening packages containing radioactive materials.

15. The rules specified in Appendix G of REgulatory Guide 10.8 will be followed for the general use of radioactive material.

16. The emergency procedures specified in Appendix H of Regulatory Guide 10.8 will be followed.

17. Area survey procedures will be followed as outlined in Appendix I of Regulatory Guide 10,8.

XXXXXXXX

WASTE DISPOSAL

18. 1. Liquid waste will be disposed of (check as appropriate)

__X__ By commercial waste disposal service (see also item 4 below).

__X__ In the sanitary sewer system in accordance with §20.303 of 10 CFR Part 20.

__X__ Other (specify): Liquid Scintillation Counter Waste (see also item 5 below)

2. Mo-99/Tc-99m generators will be (check as appropriate)

__X__ Returned to the manufacturer for disposal.

__X__ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

__X__ Disposed of by commercial waste disposal service (see also item 4 below).

_____ Other (specify): _____

3. Other solid waste will be (check as appropriate)

__X__ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

__X__ Disposed of by commercial waste disposal service (see also item 4 below).

_____ Other (specify): _____

4. The commercial waste disposal service used will be

Radiac (Name) Brooklyn, N.Y. (City, State)

NRC/Agreement State License No. 31-17528 ~~1944-1879~~

5. A special amendment was applied for in June 1980 for the incineration of Liquid Scintillation Counter Waste.

6. A second commercial Waste disposal Service that may be used:

Radiation Service Organization, Laurel, Md.
MD-33-021-02

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19. Therapeutic use of Radiopharmaceuticals.

The procedures outlined in Appendix K of Regulatory Guide 10.8 will be followed with the exception that excreta from patients may not be collected and stored for decay in accordance with section 20.303 of 10 CFR 20.

Procedures for bioassay of personnel preparing and administering oral solutions of iodine-131 for therapeutic doses will be in accordance with the criteria outlined in Regulatory Guide 8.20 dated September 1979.

(a) The preparation of an iodine-131 therapy dose is done by a Nuclear Medicine Technologist. The technologist, wearing rubber gloves, initially opens the container(s) in a fume hood with adquate air flow and adjusts the volume (if necessary) to obtain the desired activity of Iodine-131. The adjusted dose is confirmed by measuring in a dose calibrator and the results recorded.

The therapy dose, in the original lead shipping container is placed on a cart with extra shielding (if necessary), a survey meter and other necessary items (water, straws, rubber gloves, etc.) for transport to the patient's room.

The nuclear physician assures that the patient is isolated and that no further examinations or lab tests are needed. He explains safety procedures to the patient and nursing staff. He also supervises or performs the administration of the Iodine-131 therapy dose. A bed side table is covered with disposable absorbant paper and the lead container (s) placed on the paper. Rubber gloves are worn throughout the procedure.

The vial, remaining inside the lead shield is carefully opened and the patient then drinks the solution through a straw along with several rinses of fresh water. After administering the dose, all equipment is returned to the Nuclear Medicine Department for monitoring and proper disposal.

The RSO or his designate will monitor the area and check to see that the proper forms are in the patient's chart and proper signs are posted on the patient's room door.

(b) The preparation of P-32 as soluble phosphate for the treatment of polycythemia vera is done by a Nuclear Medicine Technologist. Wearing rubber gloves, the proper volume and activity (2 to 4 mCi) is withdrawn into a plastic shielded syringe and the activity is verified in a dose calibrator in the presence of the attending nuclear physician. The physician usually administers the dose IV unless there is some doubt about getting into the vein, then he will carefully transfer the dose to a cup and administer the dose orally.

19. Therapeutic use of Radiopharmaceuticals (con't)

(c) The preparation of P-32 as Colloidal Chromic phosphate is done by a Nuclear Medicine Technologist. The technologist, wearing rubber gloves, will withdraw the desired volume of solution (containing 3-12 mCi P-32) in a plastic syringe and verify the activity in a dose calibrator in the presence of an attending Nuclear Physician. The solution is then added to 50 ml. of saline.

A catheter is placed in the patient by a surgeon (usually the peritoneal cavity). A solution of 300 uCi. of Tc-99m sulfur colloid in 500 ml. of saline is put into the cavity through the catheter.

A one-minute gamma camera picture is taken to assure that there is an even distribution of the saline solution in the cavity. If the distribution is satisfactory, the attending nuclear physician will administer the P-32 saline solution through the catheter. If there is no leaking around or through the catheter, it is either clamped (for further use) or removed.

All contaminated articles are removed to be monitored and proper disposal.

20. Therapeutic use of Sealed Sources.

(a) Radioactive sealed sources of radium, strontium-90 and Cesium-137 are stored in Room BA 94 located in the basement (attachment # 3 Figures 1 and 8) and is part of the Radiation Therapy Department. The radium, consisting of needles and tubes, is stored in 2 conventional lead safes each having 4 inch thick lead walls. An additional 2 inch thickness of lead bricks is added along the wall adjacent to the unrestricted hallway. A third lead safe is located in the restricted area above the Cobalt-60 Teletherapy room (attachment # 3 Figure 1, 9 and 10).

(b) Source handling is done with 12 inch forceps with the operator standing behind an L-block shield (with a lead glass viewing window). Special clamps, chucks and vises are provided to assemble the various applicators (Ernst, Fletcher, etc).

(c) Instructions for nursing care of patients will be outlined in Appendix L of Regulatory Guide 10,8 .

(d) Personnel preparing applicaters wear TLD finger rings. Physicians handling the sources in the OR wear pocket dosimeters (radium only). Our Cesium-137 sources are all designed and used in after-loading techniques.

20. (e) Two stainless steel push carts have been modified and are used to transport sources from storage to the place of use. Each cart has a 1.5 inch thick lead well that measures 4" wide x 14" long x 3" deep. An additional 1.5 inches of lead is placed at the end of the well that is nearest the operator when pushing the cart. Several 1" and 2" thick lead pigs and transport dollies with long handles are also available for transporting sources.

(f) The Radiation Safety Officer is the custodian of brachytherapy sources. A sign-out and sign-in log book is immediately available near the L-block shield in the source preparation room. The log is contained in a bound note book. Information obtained includes the date, sources in or out, activity of each source, applications and initials of person removing or returning sources.

A complete inventory is done each 6 months at the time of leak testing the sources.

Following treatment, each patient and room is surveyed with a survey meter to determine if all sources were removed. The sources are visually checked by one of the therapy technologists for damage, counted, and returned to a specific location in one of the lead safes. The number of sources returned is then entered into the log book.

(g) Each patient and room will be surveyed with a radiation survey meter at the conclusion of treatment and after the sources have been transported back to the preparation and storage room. The number of sources removed and the results of the survey will be logged in a separate log book. The information to be recorded will include date, patient's name, number of sources removed, survey results and initials of surveyer.

21. Procedures and Precautions for use of Radioactive Gases (e.g. Xenon-133).

1 a. It is anticipated that 15 studies per week will be performed with an average activity of 15 mCi per patient (using prepackaged vials containing 20 mCi on the first of the week and decaying to about 11 mCi by Friday).

b. The maximum possession limit of Xenon-133 will not exceed 1.5 curies.

2. a. The areas for use and storage of Xenon-133 are located in the south west corner of the nuclear medicine department some 40 feet from any unrestricted area. The vials (20 mCi each) are stored in lead shipping containers behind 2 inch thick lead bricks (attachment # 3 Figures 2 and 3).

21 2. b. Xenon-133 vials are stored in the dose preparation laboratory, Room BG-11 which is 7.5 x 9' with an 8 foot ceiling. The air is supplied to the room from slot inlets in the ceiling, located on the long sides of two rectangular fluorescent light fixtures (slots are 3/8" x 34" long). A 2 foot x 2 foot exhaust vent is also located in the ceiling. There is no recirculation of air. The air flow rate is 200 cfm.

Xenon-133 is used in Room BG-17 which is 11' x 14.5' with an 8 foot ceiling. Air is supplied to the room from slots located on the long sides of two rectangular fluorescent light fixtures. The exhaust vent is also located in the ceiling. It consists of a 10" x 10" louvered portal covering a 9 inch diameter exhaust hose that goes directly to the main exhaust plenum The exhaust system goes directly to the roof with no recirculated air. The air flow rate is 300.

c. To ensure that the air flow rates are maintained in areas where Xenon-133 is used, we propose to install an air flow monitor in the exhaust duct and one in the room someplace such that the ratio of the two monitors will indicate the air flow conditions of the area. The reading of these monitors will be incorporated into the procedures to be followed for routine use of Xenon-133.

3. Procedures for Routine Use.

a. The activity of each Xenon-133 vial (20 mCi unit dose/vial) will be measured in the dose calibrator prior to administration and then loaded into the shielded calidose dispenser. The dispenser will then be connected to the Ventil-con Xenon rebreathing system and administered to the patient via this unit. A face mask will be used to prevent the patient from exhaling the Xenon into the room. Both doors to the room will be closed to create a negative air pressure in the room (indicated by an air flow monitoring system).

The entire procedure will be explained to the patient (especially instructions for a single breath) to insure the patient's confidence and cooperation.

After the patient has inhaled and exhaled 3 or 4 times the patient will then take in a slow breath and hold it (inject Xenon-133 at the beginning of this breath, start aquisition). Image until 500 K counts have been acculumulated or patient can no longer hold breath.

Set the system for rebreathing. Let patient rebreath for 3 minutes. Start equilibrium image and aquire 500 K counts. Set formatter for 60 seconds and recycle.

21. 3 a (con't)

Set system to washout, turn on Xenon-133 trap and take the following views:

Four	(4)	60 second views	posterior supine
One	(1)	60 second view	right posterior oblique
One	(1)	60 second view	left posterior oblique

Return patient to supine position, remove the mask and have physician check the study.

b. The Ventil-con Xenon-133 rebreathing system is described in attachment # 4.

c. Nose clamps may be used in cases where complete face masks could not be used effectively.

4. Emergency Procedures

The patient and all personnel will be removed from the room. The doors will be closed and remain closed for a period of not less than 45 minutes. Upon re-entry, the room will be surveyed to insure that radiation levels have returned to normal.

The 45 minutes will insure 10 changes of air in the room based upon the following calculations:

$1276\ ft^3/300\ cfm = 4.25$ minutes

5. Air Concentration of Xenon-133 in Restricted Areas.

a. The maximum activity (A) used per week is estimated to be 300 mCi based on 15 patients/week and 20 mCi per patient.

b. We estimate a 20% loss of Xenon-133 (f) during patient administration, storage, and disposal.

c.1. Storage area is a (7.5 x 9 x 8) room with flow rate of 200 cfm. Thus the volume of air available per week for dilution is:

$$V = 200\ cfm \times 6.8 \times 10^7\ ml/40\ hr\ wk = 1.36 \times 10^{10} ml$$

Maximum Activity per week is:

$$A = \frac{20 mCi}{patient} \times \frac{15\ patients}{week} \times 1 \times 10^3 \frac{uCi}{mCi}$$

$$A = 3 \times 10^5\ uCi/wk$$

The concentration, C, of Xenon-133 gas within the storage area for a 40 hr week is found from:

$$C = (a \times f)/V = \frac{3 \times 10^5 \times 0.2}{1.36 \times 10^{10}}$$

$$C = 4.4 \times 10^{-6}\ uCi/ml$$

5 c1 (con't)

This verifies that the MPC of 1×10^{-5} uCi/ml for a restricted area will not be exceeded.

2. Imaging area is a (11 x 14.5 x 8) room with air flow rate cf 300 cfm. Thus, the volume of air available per week for dilution is:

$V = 300 \text{ cfm} \times 6{,}8 \times 10^{7} \text{ ml}/40 \text{ hr wk} = 2.04 \times 10^{10} \text{ ml}$

$A = 3 \times 10^{5}$ uCi/wk

The concentration of Xenon-133 gas within the imaging area for a 40 hour week is found from:

$$C = \frac{3 \times 10^{5} \times 0.2}{2.04 \times 10^{10}}$$

$C = 2.9 \times 10^{-6}$ uCi/ml

This verifies that the MPC of 1×10^{-5} uCi/ml for a restricted area will not be exceeded.

6. Adsorption onto Charcoal Traps

The Xenon Trap from Radx has a GM detector system monitoring the exhaust port of the trap. It is designed in such a fashion that when the unit is first turned on the alarm activates for a few seconds to indicate that the system is functional. The alarm is set to activate when the concentration in the exhaust port exceeds 2×10^{-2} uCi/ml. The exhaust will empty into the imaging room and has been considered as part of the Xenon loss in item 5.b. of this section.

Saturated filters (indicated when alarm system will not reset) will be plugged and placed in storage behind a minimum of ½ inch lead shielding in Room BB44 for a period of not less than 15 half lives (Attachment # 3, Figure 4). Since the filter is plugged and completely sealed,it is not anticipated that it will contribute to the Xenon-133 air contamination.

22. Radioactive Material in Animals

No animal research using radioactive material have been done for the past two years. However, in the event of such a research project the Radiation Safety Committee will require the following information:

a. A description of the animal housing facilities.

b. A copy of instructions provided to animal caretakers for handling animals, animal waste and carcasses.

c. Instructions for cleaning and decontaminating animal cages.

22. (con't)

d. Procedure for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

e. Other information as specified in our Radiation Safety Guide (page 2 of attachment # 2).

23. Procedures and Precautions for use of Radioactive Material Specified in item 6.b.

In addition to the radiation safety procedures listed above, a bioassay program for tritium will be followed as specified in the NRC Guidelines for Bioassay Requirements for Tritium, dated October 19, 1977.

There are no plans for iodination or tritiation programs at this time.

A Radioactive Drug Research Committee has been appointed and approved by the FDA to review and consider research projects using radioactive labeled drugs in accordance with provisions of section 361.1 of 21 CFR 361.

CURRICULUM VITAE

Eduard V. Kotlyarov, M.D., Ph.D., D.Sci.(Med.)

ATTACHMENT #1

BORN: October 20, 1942, Moscow, U.S.S.R.

MARITIAL STATUS: Married - one child

BUSINESS ADDRESS:
Washington Hospital Center
Department of Nuclear Medicine
110 Irving Street, N.W.
Washington, D.C. 20010
202-541-6066

EDUCATION:

High School
1949-1959
First Moscow High School
B Pereyaslavaskaya 3
Moscow, U.S.S.R.

Medical
1959-1965
First Moscow Medical Institute
Department of General Medicine
Moscow, U.S.S.R.
(Diploma M.D. No. 335221)

Philosophy
1969-1971
Political University
Philosophy Department
Moscow, U.S.S.R.
(Diploma No. 8088)

Mathematics
Moscow Institute of Electronic and Mechanical Engineering
Department of Applied Mathematics
Student card no. BM-71034
1 year of 3 year course of M.S. in Mathematics

Business Administration
January 1978-January 1979
The University of Nebraska at Omaha
Graduate College Program - Master of Business Administration - 15 credit hours
(Graduate Management admission test RN 20671, November 1977)

September 1979-present
George Washington University School of Government and Business Administation - Master of Hospital Business Administration - Graduate College Program

MEDICAL POSTDOCTORAL TRAINING:

Residency (U.S.S.R.)
1965-1966
Department of Radiology and Roentgenolgy
First Moscow Medical Institute
Moscow, U.S.S.R. (Certificate No. 506)

Fellowship
1973
The Central Institute of Continuing Medical Education
Department of Endocrinology
"Special Course for Endocrinology Department Chiefs"
Moscow, U.S.S.R. (Certificate No. 287699)

Fellowship
1975
Second Moscow Medical Institute
Department of Continuing Education for Professors of Medical Institutes - "Special Course of Continuing Education of the Professors of Radiology"
Moscow, U.S.S.R. (Certificate No. 658)

Fellowship October 1975- January 1976	University of Miami School of Medicine Program for Foreign Medical Graduates "Intensive Course of Postgraduate Medicine" Miami, Florida (in Spanish) (Diploma No. 31-127)
January 1976	ECFMG Certificate No. 262-232-2
Residency (USA) September 1976- August 1977	Washington University School of Medicine Mallinckrodt Institute of Radiology Division of Nuclear Medicine (Certificate of training) St. Louis, Missouri (American Board of Nuclear Medicine certified September 1976)
June 1977	FLEX Examination (State Board No. 74553)
January 1978-	Ultrasound Clinical Experience Department of Radiology Nebraska University Medical Center (Certificate of training)

SCIENTIFIC DEGREES:

April 15, 1968	First Moscow Medical Institute Candidate of Medical Sciences (Subspeciality Radiation Science) Equivalent of U.S., Ph.D. (Diploma No. 018629)
May 17, 1971	First Moscow Medical Institute Doctor of Medical Sciences (Subspecialty Radiation Science) Equivalent of U.S. Sci,D. (Med.) Certificate of Scientific Council Moscow, U.S.S.R.
LICENSE:	State of Missouri - No. 35825 (1977) State of Nebraska - No. 14132 (1977) District of Columbia - No. 11451 (1979)

SPECIALTY BOARD CERTIFICATION:

1976	American Board of Nuclear Medicine, Diploma No. 04068

AWARDS AND RECOGNITIONS:
Medical Student 1962-1965

1962	First Moscow Medical School I Sechenov prize in Premedical Sciences
1963	All-Russian Medical School Student, Scientific Committee prize in Oncology

1964	First Moscow Medical School Prize in Foreign Medical Literature Review Competition
1965	First Moscow Medical School Award in Radiology (Nuclear Medicine)
1970	Award Diploma of the First Moscow Medical Institute for "The Best Scientific Work of the Year 1970" (Kinetics of Iodine and Technetium Metabolism)
1971	"Recommendation to publication of dissertation D.Sci (Med.) as a Monography" - Decision of Scientific Council of Internal Medicine of First Moscow Medical Institute (1971) (Diagnosis and Therapy of Thyroid Gland Diseases)
1972	Award Diploma and Bronze medal of All-Union Exhibition "The National Achievements of U.S.S.R." (Method of radioisotope renometry with whole body counter)
1972	First Moscow Medical Institute Recognition Award for 7 years of successful clinical and teaching service
1977	American Medical Association Physician's Recognition Award in Continuing Medical Education (Expires February 1, 1980)
1977	Omaha Mid-West Clinical Society, 45th Annual Assembly Premier Award for Research Scientific Exhibit "Assesment of Myocardial Blood Flow with 201-Tl-Chloride"
1978	Omaha Mid-West Clinical Society, 46th Annual Postgraduate Assembly, Premier Award for Research, Scientific Exibit, Perfusion Studies in Ischemic Heart Disease."
1978	Physician's Recognition Award in Continuing Medical Education (Expires November 1, 1981)

ACADEMIC APPOINTMENTS:

September 1966- October 1975	First Moscow Medical Institute Assistant Professor, Department of Radiology and Roentgenology
February 1976- August 1976	Washington University School of Medicine Mallinckrodt Institute of Radiology Research Assistant, Division of Nuclear Medicine St. Louis, Missouri

September 1976- August 1977	Washington University School of Medicine Mallinckrodt Institute of Radiology Assistant in Radiology, Division of Nuclear Medicine St. Louis, Missouri
August 1977- March 1979	University of Nebraska Medical Center Associate Professor of Radiology Omaha, Nebraska
February 1979	George Washington University Medical School Associate Professor of Radiology (Clinical) Washington, D.C.

CLINICAL AND ADMINISTRATIVE APPOINTMENTS:

April 1969- October 1975	First Moscow Medical Institute Director, Central Interclinical Radioisotope Diagnostic Laboratory Moscow, U.S.S.R.
March 1974- October 1975	First Moscow Medical Institute Deputy Director, Radiology Clinic Moscow, U.S.S.R.
August 1977- March 1979	University of Nebraska Medical Center Attending Nuclear Medicine Physician Omaha, Nebraska
February 1979- Present	Washington Hospital Center Associate Chairman of Nuclear Medicine Department Washington, D.C.

PROFESSIONAL SOCIETY AND COMMITTEE APPOINTMENTS:

1965-1975	Nuclear Medicine Society of U.S.S.R.
1969-1975	Board of the Moscow Nuclear Medicine Society
1971-1974	Secretary of the Board of the Moscow Nuclear Medicine Society
1969-1974	Radiology (Nuclear Medicine) Section of the Pharmacy of the U.S.S.R.
1970-1975	Endocrinology Society of U.S.S.R.
1970-1974	Nuclear Medicine Committee of the Ministry of Public Health
1969-1975	First Moscow Medical Institute Co-director of the two-year residency project in Nuclear Medicine
January 1977	Society of Nuclear Medicine, U.S.A.

October 1977	American College of Radiology
October 1977	American College of Nuclear Physicians
December 1977	American Medical Association
December 1977-1979	Nebraska Medical Association
December 1977-1979	Nebraska Medical Foundation
December 1977-1979	Greater Omaha Medical Society
February 1978	Radiologists Business Managers Association
March 1978	American Association for the Advancement of Science
April 1978	Health Physics Society
May 1978	Association of University Radiologists
November 1978	The Radiological Society of North America
March 1979	District of Columbia Medical Society
October 1979	Society for Medical Decision Making (Founding member)

LANGUAGE ABILITIES:

Russian - Mother tongue

Spanish - Fluent (Family language)

English - Fluent

SUPPLEMENTARY:

Author;s Licenses Given for methods in Nuclear Medicine and Encocrinology	4
Reports on International Conferences and on Conferences in the U.S.S.R. (national and state level)	31
Reports on Conferences in the USA (national and state level)	18
Reports on Internation Conferences	6
Published Monographs	2
Articles in Scientific Journals (including abstracts)	121
Scientific Exhibits (USA)	3
Grant supported new radiopharmaceutical research (USA)	2
Dissertation of E.V. Kotlyarov (Candidate of Medical Sciences - Ph.D.) (Doctor of Medical Sciences - Sci.D.)	2
Dissertation of other Ph.D., officially supervised by E.V. Kotlyarov (Radiation Science and Metabolism)	10
Articles on historical and political topics	4

(Russian, Spanish and English language notarized copies of all diplomas and certificates available.)

ATTACHMENT #2

PROCEDURES AND REQUIREMENTS FOR AUTHORIZATION TO USE RADIOACTIVE MATERIALS

A seperate application is required for each project that contemplates the use of radioisotopes. The Radiation Safety Committee recognizes four basic types of applications: 1) in-vitro laboratory, 2) lower animal research, 3) routine human use, and 4) non-routine human use. Each requires distinct levels of training and experience and the amount of information to be submitted . The Radiation Safety Office has copies of the necessary forms.

The Radiation Safety Committee recommends that the investigator call on the Radiation Safety Officer whenever he is contemplating a project involving radioisotopes. The RSO is more than willing to discuss the project and application with the investigator in an attempt to smooth out potential problems before the protocol is submitted, and to point out those areas that may require specific attention.

All investigators must have a current statement of Training and Experience (Form RSO-1) and a description of the laboratory facilities (Form RSO-2) on file in the Radiation Safety Office prior to submitting application for use of radioactive materials.

Upon completion, the application should be forwarded to the Chairman of the Radiation Safety Committee. Action of the Committee will be returned through channels to the applicant.

Each authorization will expire on the last day of the appropriate calender year. Prior to the expiration date the Radiation Safety Office will send each principle investigator a memorandum (Form RSO-3) listing the current authorized projects with a request to review the procedures and delete those studies that will not be used during the next year. The signed memorandum should be returned to the Radiation Safety Office for approval by the Committee.

If questions regarding details of an application should arise in the course of the Committee's consideration, the investigator will be invited to meet with the Committee and discuss the details of his proposal.

IN-VITRO LABORATORY APPLICATIONS

Investigators applying for this tyep of use must meet the following requirements and submit Form RSO-4 to the Chairman of the Radiation Safety Committee:

1. Submit a statement that by product material will be used only by; or under the direct supervision of, individuals who have received:

   (a) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

IN-VITRO LABORATORY APPLICATIONS (con't)

(b) At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation instrumentation and biological hazards of exposure to radiation appropriate to the type and forms of by product material to be used.

2. Provide administrative controls and provisions relating to procurement of byproduct material, procedures, record keeping, material control and accounting and management review necessary to assure safe operations.

LOWER ANIMAL RESEARCH APPLICATIONS

Investigators applying for this type of authorization must submit Form RSO-4 and satisfy the preceding requirements and must also have experience or training in the handling of radioactive animals.

Applications must be accompanied by a copy of the project protocol submitted to the Washington Hospital Center Research Committee which should include items as:

1. The type of animal to be used, how it is to be cared for, and the maximum and the average number to be used in the study and method for disposal.

2. The isotope and amount to be given to each animal, the frequency that the dose is given, and the effective half-life of the isotope in the animal.

3. The estimates of the exposure rates at one meter from the animal cages.

4. A list of safety precautions that will be given to the Animal Research Facilities personnel.

5. Methods of Waste Disposal, particularly those of urine and stools and calculations of the daily amounts of radio-activity to be disposed of into the sewer or air.

ROUTINE HUMAN USE APPLICATIONS

A listing of acceptable routine uses as defined by the Nuclear Regulatory Commission appears in the CFR, Title 10, Part 35, of this manual.

Investigators applying for this tyep of authorization must submit From RSO-5 and satisfy the NRC requirements for training and experience as stated in Regulatory Guide 10.8. These requirements are listed in Appendix A of this manual.

NON-ROUTINE HUMAN USE APPLICATIONS

Physicians who wish to use radioactive materials in human subjects must meet the requirements for training and experience as described in the NRC Reglatory Guide 10.8 before their application is approved. These requirements are reprinted in Appendix B of this manual.

Applications must be submitted on From RSO-5 and be accompanied by a copy of the project protocol submitted to the Washington Hospital Center Research Committee, which should include the following information:

1. A narrative description of the project, which shall include the title of the project, a statement of the purpose and justification for the use of radioactive materials, the methods of administering doses, and the anticipated results.

2. A reference to previous work published by the applicant or others concerning animal experimentation or human use. If no prior reference work is available and basic knowledge concerning the investigation is meager, pertinent animal studies by the investigator regarding the biological fate, excretion and toxicity data of the radioisotope compound must be included.

3. The number, age, nature of disease process, and the methods of selection of patients to be studied, together with similar data on any control subjects.

4. A confirmation that an informed consent must be obtained from patients who will participate in the study. If the study plans provide for use of radioactive material for normal human subjects, the minimum age of the subjects must be specified and the fact that they will be fully informed of possible radiation or other hazards of such studies must be included.

5. The chemical and physical characteristics of the radioisotope (half-life, nature and energy of emission, mode of decay, etc.).

6. The estimated dose range in millicuries of the radioisotope to be used and the rationale of using the estimated dose.

7. The estimated radiation dose delivered to the subjects, based on the expected half-life of the radioisotope in various tissues of the body. (The Committee requires a clear, concise calculation of the anticipated whole body and critical organ exposure and burden in rems and a statement of the period of such exposure and the potential radiation hazards, if any. The formula used for such calculations should be clear, with all terms defined and the source and estimated reliability of the formula should be indicated. Assumptions used for estimates should be stated.)

8. The effects of complementary or of supplementary drugs on radioisotope distribution or excretion.

9. The methods of waste disposal, particularly those for urine, stools, and exhaled air, and calculations of the daily amounts of radioactivity to be disposed of into the sewer or air.

10. The methods to determine the radioisotopic calibration, the methods of processing to insure chemical purity, sterility, and absence of pyrogenicity, etc. of the radioisotopic compound; if such a compound is not obtained as a pre-calibrated, refined, sterile and pyrogen-free radiopharmaceutical.

11. The safety precautions that will be initiated to protect the patient, other patients in the vicinity, and the patient care staff and adjunct personnel.

12. A statement of the resources and facilities available to the investigator.

13. The estimated time needed to complete the study.

The investigator must immediately notify the Chairman of the Radiation Safety Committee if a patient exhibits any adverse reactions to the radiopharmaceutical administered. The investigator should describe the reaction and include his interpretation of the nature and cause of the reaction. The chairman can then decide whether or not the project should be continued, modified, or terminated, pending review of the whole Committee.

TRAINING AND EXPERIENCE WITH RADIOACTIVE MATERIALS

NAME: _____ DATE: _____

TRAINING:

Type of Training	Where trained	Duration	On the job	Formal course
A. Principles and Practices of Radiation Protection				
B. Radioactivity Measurement Standardization and Monitoring Techniques and Instruments				
C. Mathematics and Calculations Basic to the Use and Measurement of Radioactivity				
D. Biological Effects of Radiation				
E. Other:				

EXPERIENCE WITH RADIATION (Actual Use)

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use

_____
Signature

LABORATORY FACILITIES FOR HANDLING RADIOACTIVE MATERIALS
(Type or print all information)

To : Chairman, Radiation Safety Committee

From: (NAME)_____, (DEPT.)_____ (DATE)_____

Laboratory location_____
(ROOM #'s)

Description of utilities (electrical, plumbing, ventilation) available.
Description of storage area for radioactive materials.
Methods for waste disposal.
Methods for detection and prevention of radiation exposure and contamination.

RADIATION DETECTION INSTRUMENTS

Type of Instrument (Make & Model No.)	Number Available	Radiation Detected	Sensitivity Range MR/HR	Window Thickness MG/CM^2	Use Monitoring, Survey, Measure

SIGNATURE OF APPLICANT_____

WASHINGTON HOSPITAL CENTER

110 IRVING STREET, N.W. • WASHINGTON 10, D. C.

DATE:

MEMORANDUM

To: Chairman, Radiation Safety Committee

From: _____
(Department and Number)

SUBJECT: RENEWAL OF AUTHORIZATION FOR USE OF RADIOACTIVE MATERIALS.

Authorization for the use of the following radioactive materials will expire on _____. I have reviewed the authorizations listed below and deleted those procedures which are no longer used. I hereby request the continued authorization of the remaining studies.

Authorization Number	Nuclide	Chemical Compound	Study

_____
(Signature of Principal Investigator)

Authorization for the continued use of the above radioactive materials is approved under the conditions assigned to the original authorization.

_____ _____
(Authorization expires) (Chairman, Radiation Safety Committee)

_____
(Radiation Safety Officer)

RSO-3

APPLICATION AND AUTHORIZATION FOR LABORATORY USE OF RADIOACTIVE MATERIALS

TO:	Chairman, Radiation Safety Committee			
FROM:	Name	Department	No.	Date

APPLICATION:

Element and mass number	Chemical and/or physical form	Possession limit

Use:

(Signature of Principal Investigator)

TO:	Name	Department	No.	Date
FROM:	Chairman, Radiation Safety Committee			

AUTHORIZATION:

◯ APPROVED ◯ DISAPPROVED

Authorization for the use of the radioactive material described above is approved under the conditions published in the Procedural Manual for Radiation Safety and the Use of Radioactive Materials at the Washington Hospital Center, which complies with the requirements of the U. S. Nuclear Regulatory Commission and is issued under the authority of the NRC Byproduct Material License.

Conditions numbered _____ printed on the reverse side of this page shall apply to this authorization.

Authorization No.	Chairman, Radiation Safety Committee
Authorization expires:	Radiation Safety Officer

CONDITIONS

1. The radioactive material may only be used at the Washington Hospital Center.

2. The authorized user(s) shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation."

3. The radioactive materials shall be used under the supervision of _____, who shall be responsible for providing instruction, supervision, and training to all of the individuals using radioactive materials possessed under this authorization.

4. Radioactive materials specified by this authorization shall not be used in humans.

5. Needles or standard medical applicator cells containing Radium 226, Cobalt 60, and/or Cesium 137 shall not be opened by the authorized user(s) unless specifically approved by a condition in this authorization.

6. Wipe tests to determine radioactive contamination of the place of use shall be made _____ and records of test results maintained by the authorized user(s).

7. Radioactive contamination of air and sewerage shall not exceed the limits approved by NRC, Part 20, Appendix B.

APPLICATION AND AUTHORIZATION FOR CLINICAL USE OF RADIOACTIVE MATERIALS

TO:	Chairman, Radiation Safety Committee			
FROM:	Name	Department	No.	Date

APPLICATION:

RADIOACTIVE MATERIAL:
- Element-
- Chemical Form-
- Route-
- Single Dosage-
- No. of Dosages-

ESTIMATED INTEGRATED RADIATION EXPOSURE:
- Total Body Dose-
- Gonadal Dose-
- Critical Tissue-

TYPE OF PATIENTS:
- Normal Subject- Age-
- Limited Life (2 yrs.)-
- Other-

EXPOSURE TO RADIATION:
- Previous-
- Concomitant-
- Other-

PURPOSE:

(Signature of Principal Investigator)

TO:	Name	Department	No.	Date
FROM:	Chairman, Radiation Safety Committee			

AUTHORIZATION:

○ APPROVED ○ DISAPPROVED
○ APPROVED CONTINGENT ON APPROVAL BY RESEARCH COMMITTEE

Authorization for the use of the radioactive material described above is approved at the dosages indicated and under the conditions published in the Procedural Manual for Radiation Safety and the Use of Radioactive Materials at the Washington Hospital Center, which complies with the requirements of the U. S. Nuclear Regulatory Commission and is issued under the authority of the NRC Byproduct Material License.

Conditions numbered_____printed on the reverse side of this page shall apply to this authorization.

Authorization No.	Chairman, Radiation Safety Committee
Authorization expires:	Radiation Safety Officer

CONDITIONS

1. The radioactive material may only be used at the Washington Hospital Center.

2. The authorized user(s) shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation".

3. Except as otherwise specifically provided by this authorization, radioactive materials to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and nonpyrogenicity.

4. Iodine 131 labeled Macroaggregated Iodinated Human Serum Albumin, Chromium 51 labeled Human Serum Albumin, and Iodine 131 labeled Colloidal (Macroaggregated) Human Serum Albumin shall be procured from a supplier who holds an unsuspended or unrevoked license issued by the Secretary, Department of Health, Education, and Welfare, to propagate or manufacture and prepare, label, or distribute this material pursuant to Title 42, Chapter 1, Code of Federal Regulations, Part 73, "Biological Products".

5. Needles or standard medical applicator cells containing Radium 226, Cobalt 60, and/or Cesium 137 shall not be opened by the authorized user(s) unless specifically approved by a condition in this authorization.

6. Patients containing Radium 226, Cobalt 60, Cesium 137, and/or Iridium 192 implants shall remain hospitalized until the implants are removed.

7. Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less.

8. Radioactive contamination of room air and sewerage shall not exceed the limits approved by NRC, Part 20, appendix B.

9. The authorized user(s) must immediately notify the Chairman of the Radiation Safety Committee if a patient exhibits any adverse reaction to the radiopharmaceutical administered.

ATTACHMENT #3

WASHINGTON HOSPITAL CENTER

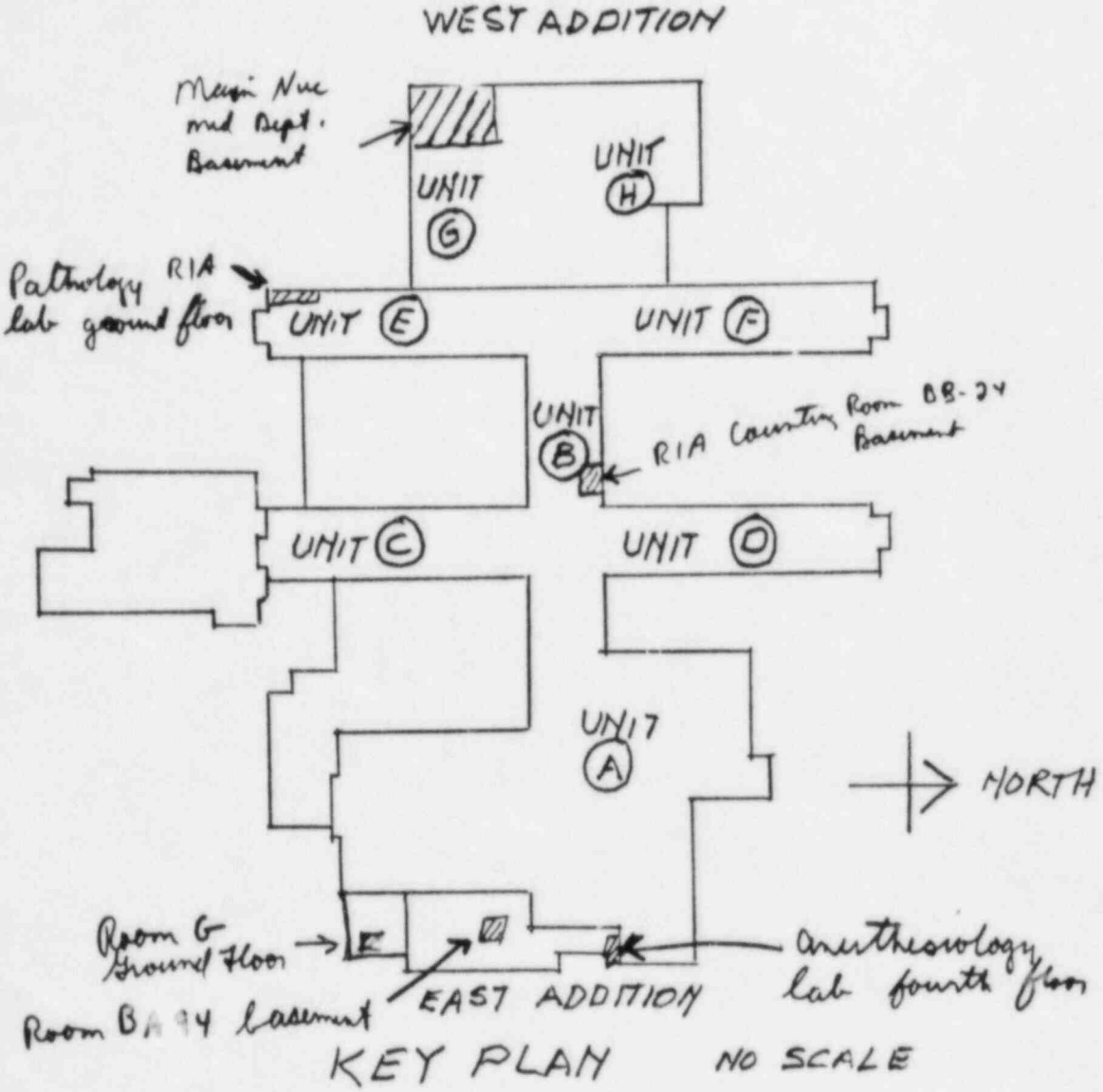


FIGURE 1

NUCLEAR MEDICAL SUITE

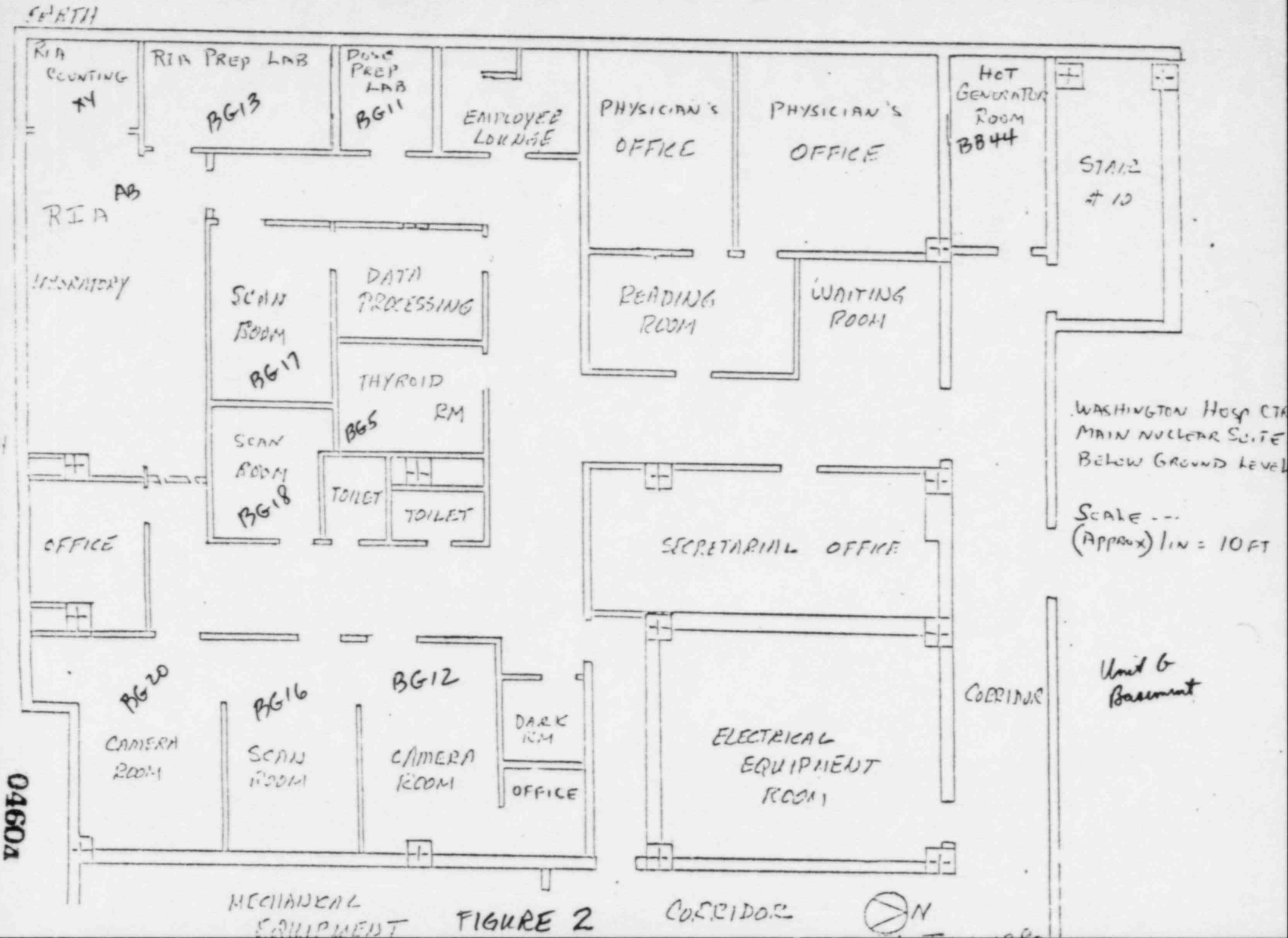
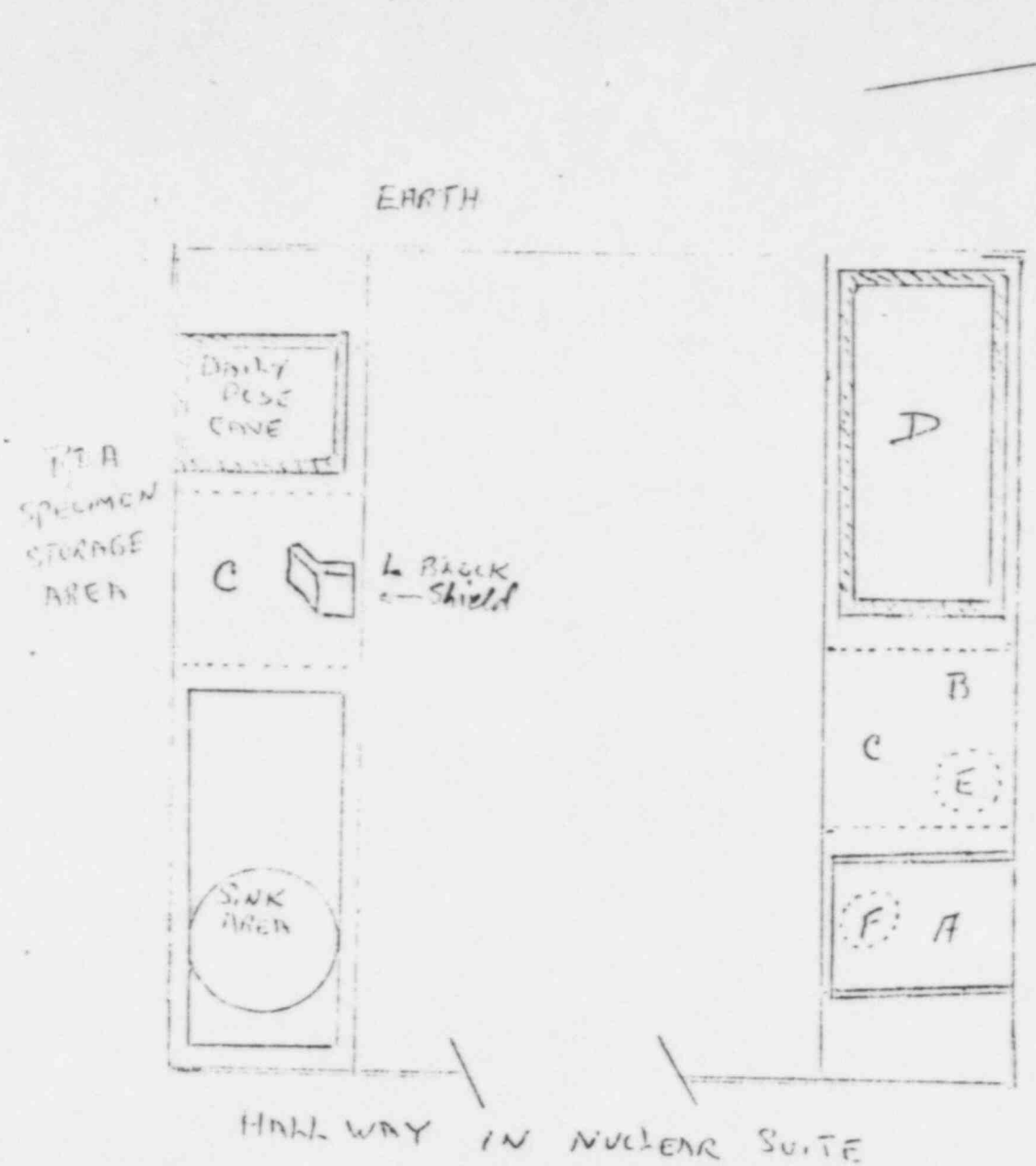


FIGURE 2

04604



WASHINGTON HOSPITAL CTR
NUCLEAR DOSE PREP LAB
- BLACK GROUPS -
BG-11

A - REFRIG FOR BIOLOGICALS
B - DOSE CALIBRATOR LOCATION
C - DOSE PREP AREA
D - BYPRODUCT STORAGE CAVE
E - S/M LOCATED IN WALL CABINET ABOVE TABLE C
F - ROOM MONITOR LOCATED ON TOP OF REFRIG.

AIR FLOW = 200 CFM

FIGURE 3

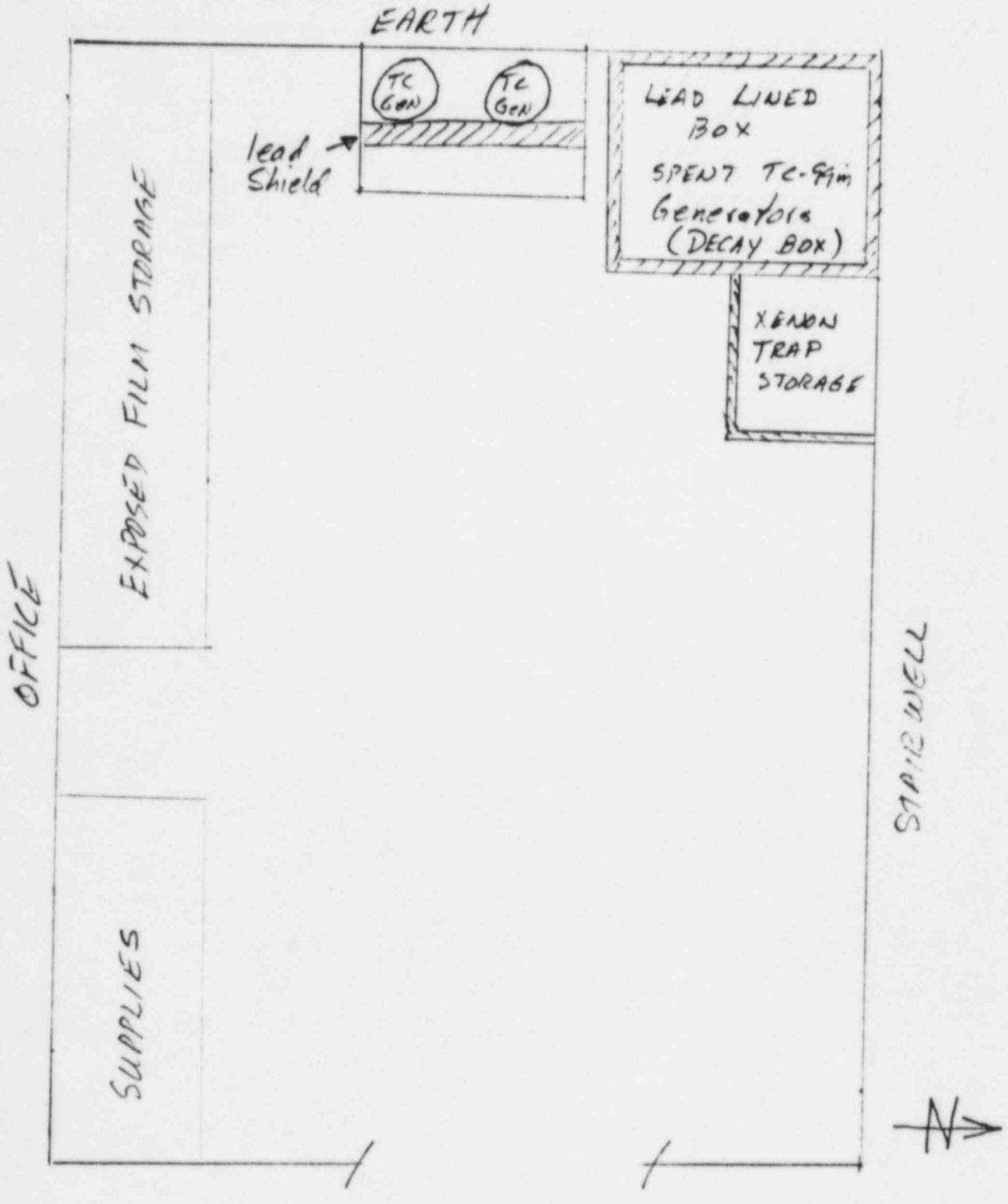
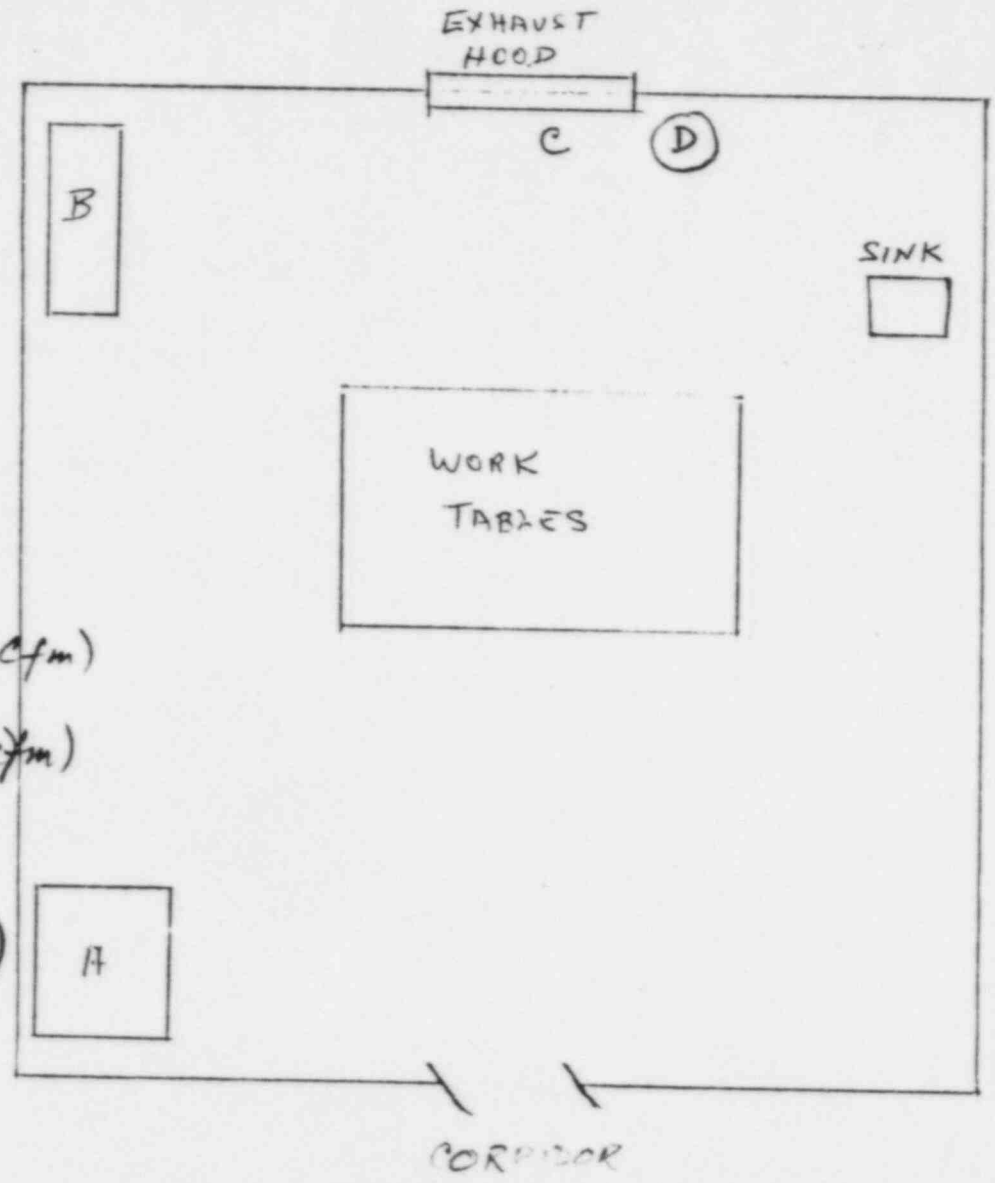


FIGURE 4

NUCLEAR MEDICINE
RM BA 44
(Shown in Figure 2 and Designated in Text as BB44)



A- REFRIGERATOR CONTAINING 125 I TAGGED SAMPLES, ETC

B- NUCLEAR-CHICAGO MARK II LIQUID SCINT COUNTING SYSTEM

C EXHAUST AIR FLOW (1800 cfm)

Room air intake (2500 cfm)

Room Exhaust (1000 cfm)

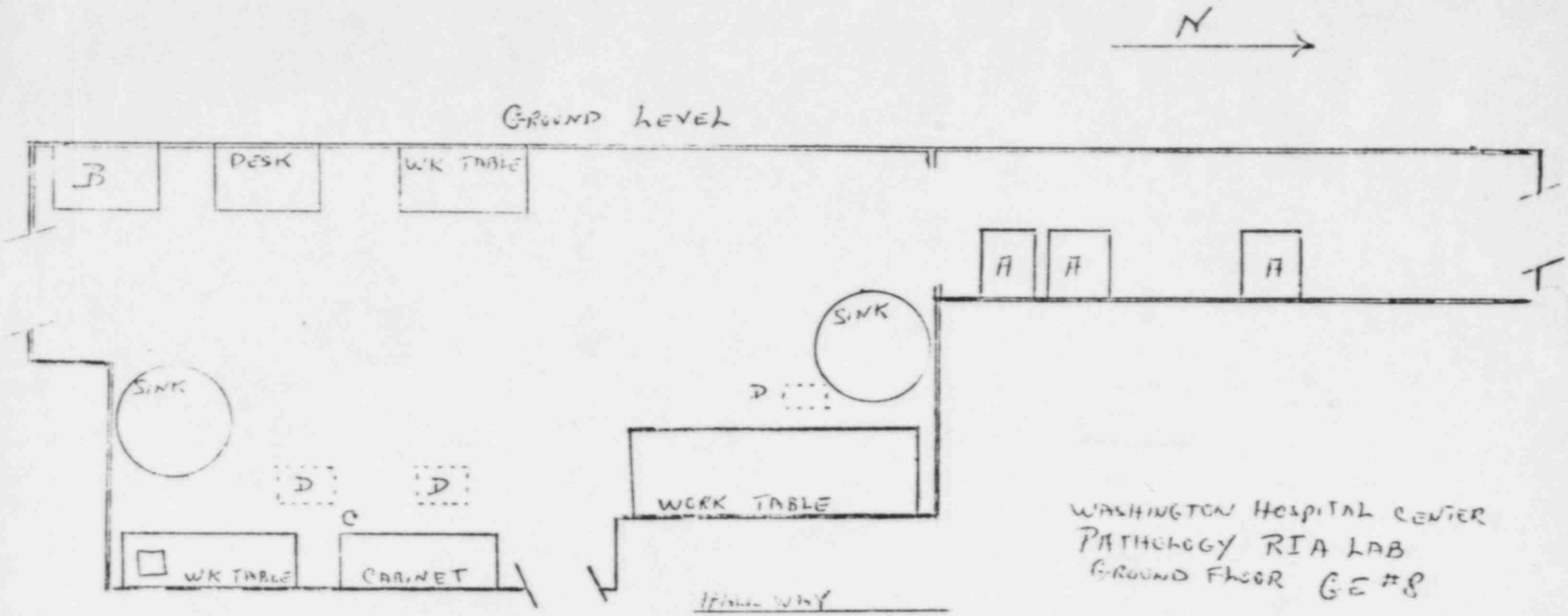
D. Liquid Scint. waste storage (55 gal commercial containers)

WASHINGTON HOSPITAL CT
RIA LAB # BB24
BELOW GROUND

SCALE 1 IN = 4 FT

JULY 10 1980

FIGURE 5



WASHINGTON HOSPITAL CENTER
PATHOLOGY RIA LAB
GROUND FLOOR GE #8

A - REFRIGERATORS FOR STORAGE OF RADIOACTIVE MATERIAL

B - SCARLE ANALYTIC GAMMA SYSTEM #1185

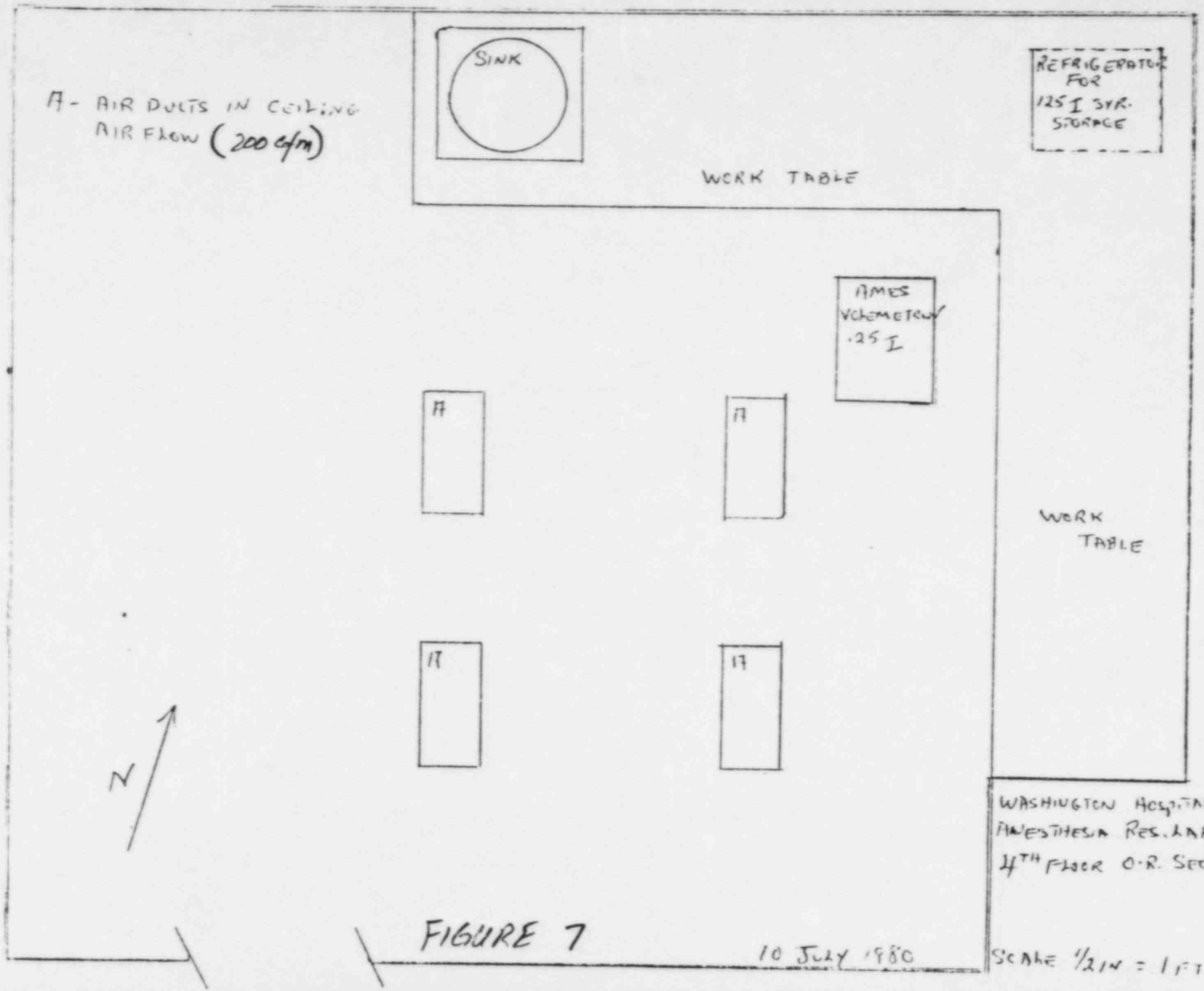
C - ATOMIC PRODUCTS SURVEY METER # 1355

D - AIR DUCTS IN CEILING AIR FLOW (300 cfm)

SCALE 1 IN = 5 FT.

10 JULY 1980

FIGURE 6


A- AIR DUCTS IN CEILING
AIR FLOW (200 c/m)
SINK
REFRIGERATOR FOR 125 I SYR. STORAGE
WORK TABLE
AMES VOLUMETRON .25 I
A
A
A
A
WORK TABLE
N
WASHINGTON HOSPITAL CTR
ANESTHESIA RES. LAB
4TH FLOOR O.R. SECTION
FIGURE 7
10 JULY 1980
SCALE 1/2 IN = 1 FT

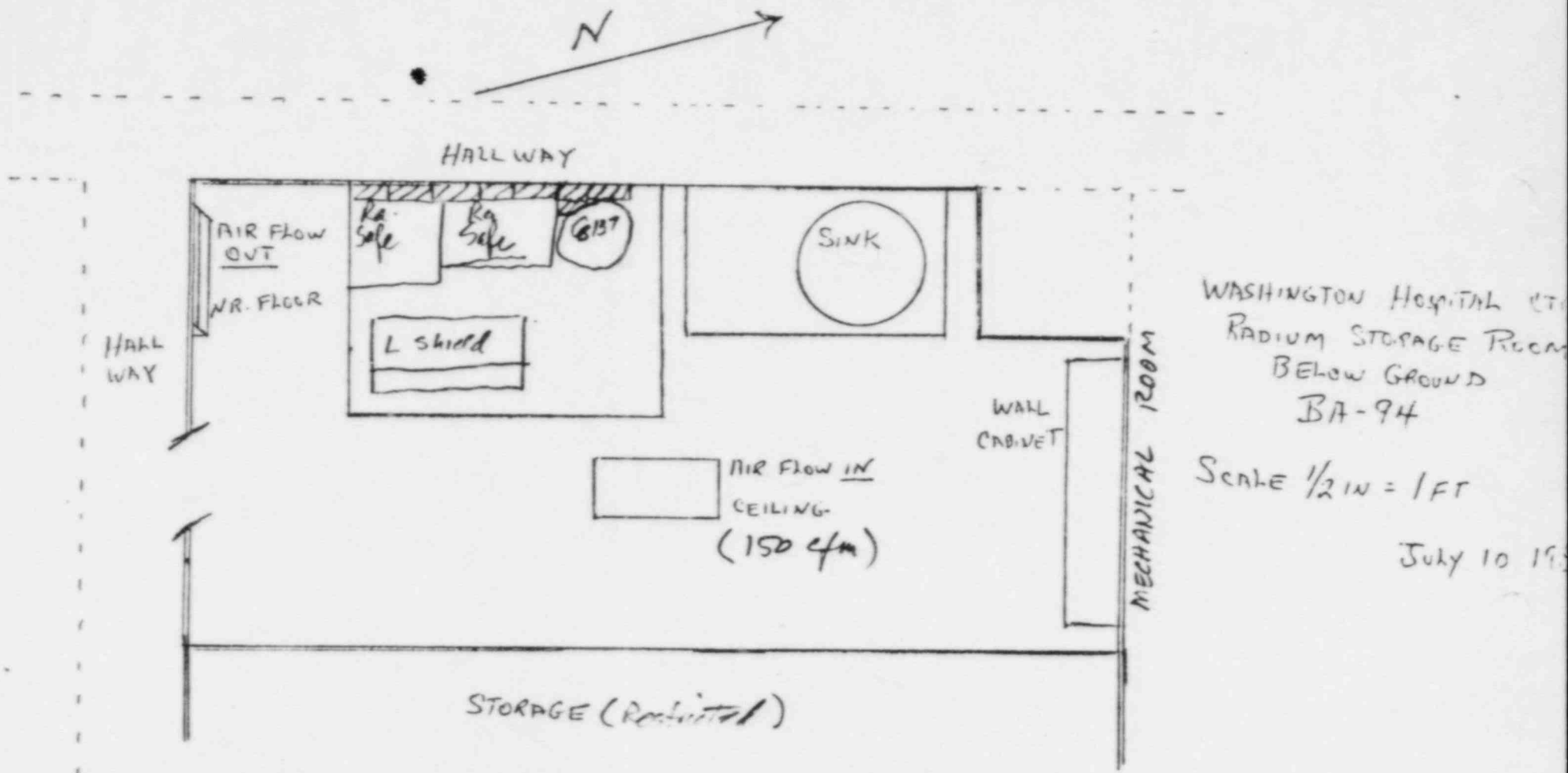

N
HALL WAY
AIR FLOW OUT
NR. FLOOR
HALL WAY
Ra Safe
Ra Safe
GB37
L shield
SINK
WALL CABINET
MECHANICAL ROOM
AIR FLOW IN
CEILING
(150 cfm)
STORAGE (Restricted)
WASHINGTON HOSPITAL CT
RADIUM STORAGE ROOM
BELOW GROUND
BA-94
SCALE 1/2 IN = 1 FT
JULY 10 19

FIGURE 8

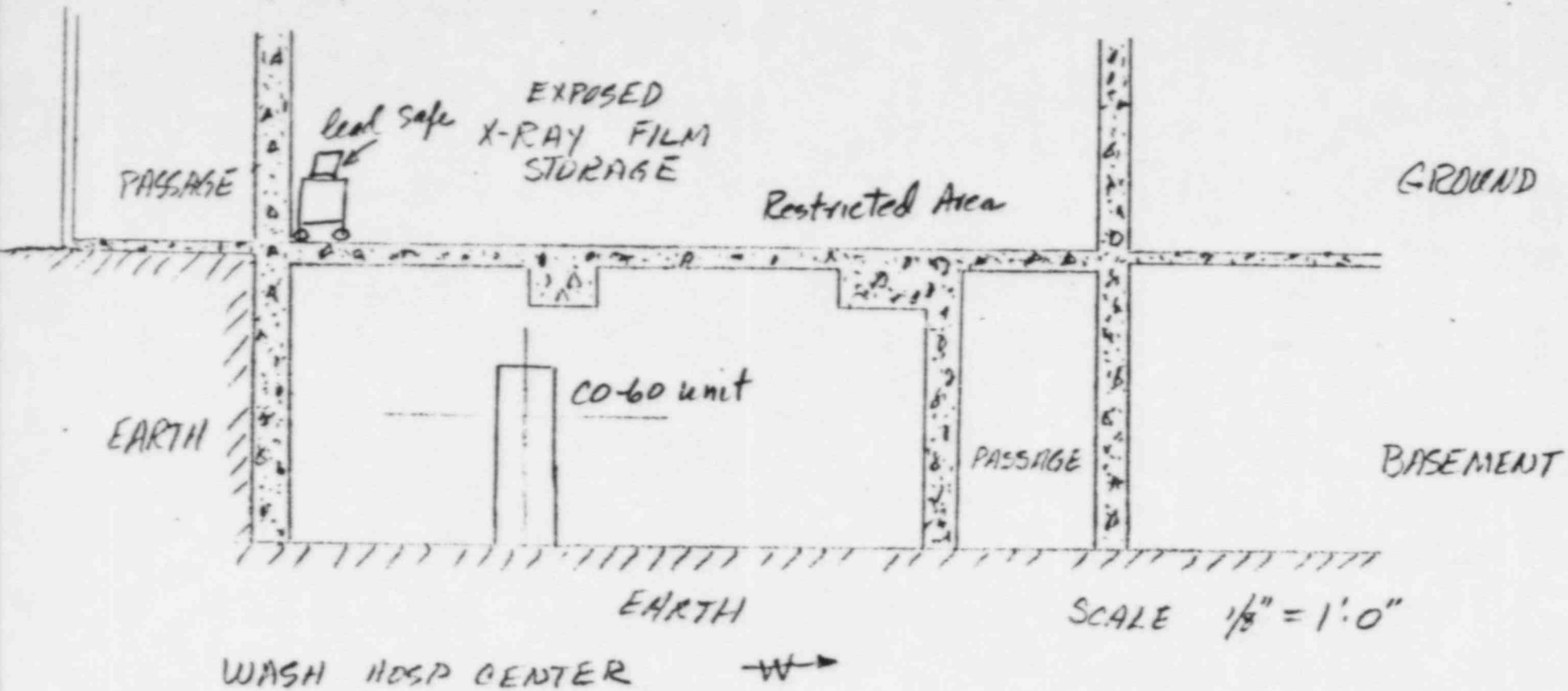

lead safe
EXPOSED
X-RAY FILM
STORAGE
PASSAGE
Restricted Area
GROUND
CO-60 unit
EARTH
PASSAGE
BASEMENT
EARTH
SCALE 1/8" = 1'-0"
WASH HOSP CENTER
W

FIGURE 9

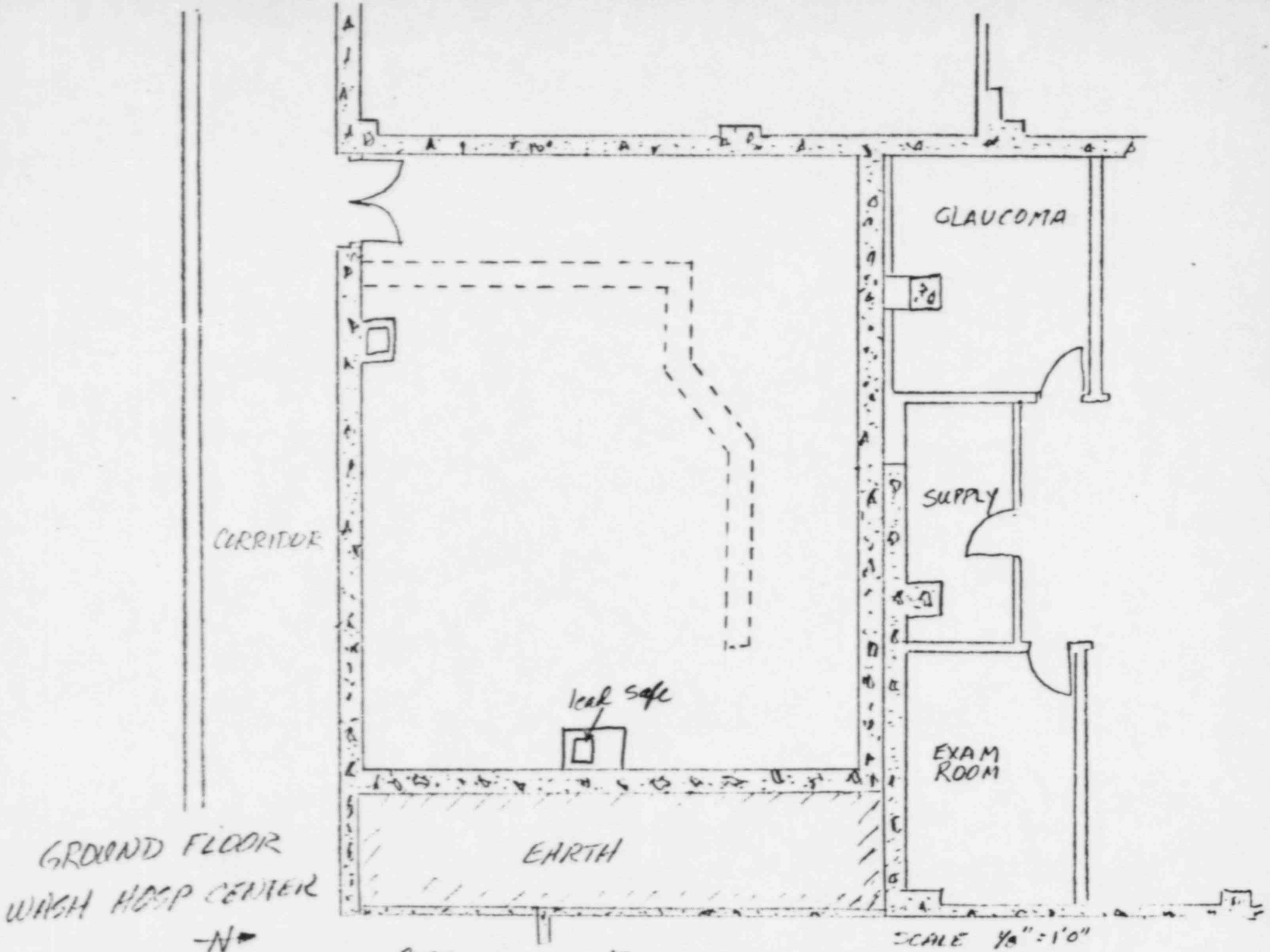
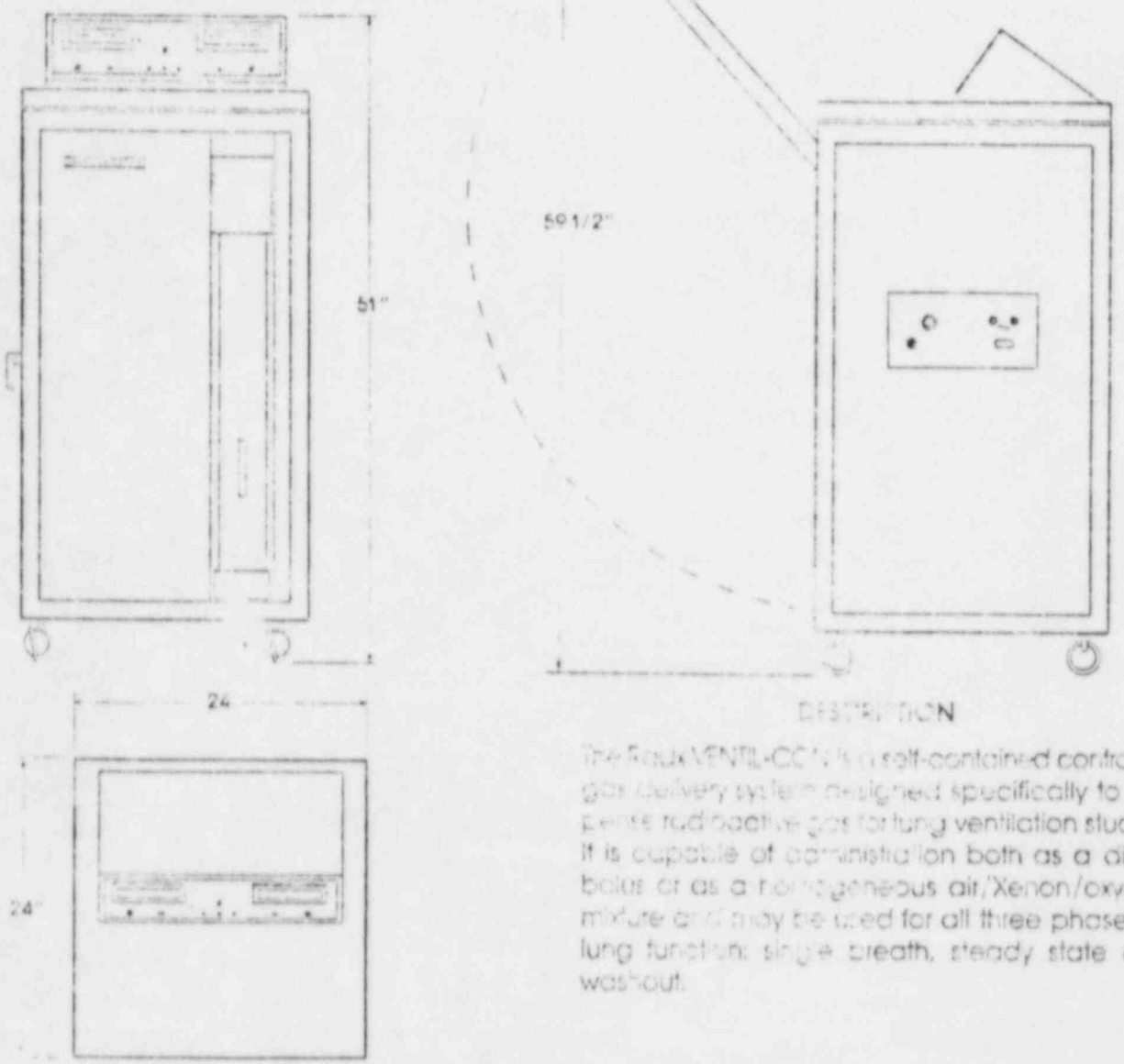

CORRIDOR
GLAUCOMA
SUPPLY
EXAM ROOM
Iron Safe
EARTH
GROUND FLOOR
WASH HOUSE CENTER
-N-
CORRIDOR
SCALE ¼" = 1'0"

FIGURE 10

ATTACHMENT II 4

Ventil-Con
Controlled
Gas Delivery System



DESCRIPTION

The RadVENTIL-CON is a self-contained controlled gas delivery system designed specifically to dispense radioactive gas for lung ventilation studies. It is capable of administration both as a direct bolus or as a homogeneous air/Xenon/oxygen mixture and may be used for all three phases of lung function: single breath, steady state and washout.

Features/Specifications

Flexible Handling Versatility—The Ventil-Con is completely self-contained in a durable, coaster-mounted console that is easily and conveniently positioned to perform the clinical study. The Ventil-Con occupies only 4 square-feet of floor space, which easily facilitates temporary storage.

Large Volume Spirometer—The Ventil-Con has a 10 liter capacity, horizontal rolling spirometer. All airway plumbing is fabricated of non-corrugated, low resistance smooth surface material (PVC tubing). The expansion/contraction factor of the balance-arm mounted spirometer diaphragm is negligible, offering a resistance of 0.05 inches of water to normal breathing. The spirometer mechanism is completely shielded with ⅛ inch lead (¼ inch option available for ^{133}Xe) for personnel safety. The spirometer volume is displayed on the control panel on a large scale analog meter and on one channel of a dual strip chart recorder (optional).

Uniform Gas Mixture—The Ventil-Con incorporates a frame mounted motor and recirculating pump to insure a homogeneous gas mixture. Equilibrium is reached within minutes of being charged.

Concentration—Concentration is continuously monitored by a calibrated Gilmont flowmeter and displayed on the large scale analog meter on the control panel and on one channel of the dual strip chart recorder (optional). The concentration may be varied by using one or all of the following controls: the evacuate mode, oxygen replenishment, and/or Xenon charge port.

Oxygen Replenishment Mode—The Venti-Con is equipped with controls that allow the addition of oxygen in three different modes from an external supply. The three modes are:

1. Auto—replaces oxygen removed by patient during "Xenon rebreathing" phase at the spirometer.
2. Manual—allows oxygen to be added to the spirometer by manually operating the momentary oxygen solenoid switch.
3. Emergency Oxygen Assist—delivers oxygen directly to the patient and is activated by a momentary switch at the head valve.

Delivery Arm—The delivery arm of the Venti-Con recesses into the cabinet during transportation or when not in use. The arm is 28 inches long, continuously adjustable up to 60 inches in height and is shielded with ⅛" lead. An additional ⅛" may be added on two sides as an option to provide adequate shielding for ^{127}Xe.

Valve Head—The Venti-Con employs the Radx patented three way valve which transfers the patient from "Stabilization" where they breathe room air, to "Xenon Rebreathing" where they are in closed loop with the radioactive gas mixture to "Washout" where the patient inhales room air and exhales out the exhaust port. Proper use of the head valve allows for a single breath study utilizing the homogeneous mixture of the Venti-Con.

Masks—A variety of masks are available for use with the Venti-Con. The unit is supplied with one "Adult Mouthpiece" and will be supplied with an Adult Mouthpiece for Bolus Injection upon request at no additional charge.

[illegible]—The Venti-Con [illegible] with a [illegible] swivel adapter which allows multiple views during the equilibrium phase of the study. The [illegible] is designed for use with the patient in the sitting position.

Carbon Dioxide Trap—The Venti-Con incorporates a rechargeable CO_2 trap using soda lime granules. These granules are normally pink, turn blue when saturated with CO_2 and are a visual indicator that the CO_2 trap needs recharging.

Xenon Gas Storage—The Venti-Con is designed in such a fashion that the only Xenon lost during a study is that which is in the patient's lungs at the start of washout. This combined with the bacteriological filter allows reuse of the Xenon gas mixture on subsequent patients. The concentration may be adjusted after each patient.

Control Functions—The Venti-Con control panel includes remote controls for the scintillation camera which allows the technologist to operate the gamma camera from the patient's side.

Power Requirements—110 volt, 60 Hz single phase 5 amp., dual fused, chassis ground

Dimensions—Height—51 inches
Width—24 inches
Depth—24 inches
Weight—Approximately 350 lbs.

Special Application—A Radx Venti-Con has been modified for Xenon-133 gas administration to determine Regional Cerebral Blood Flow by the inhalation technique of Obrist, et. al.[1] Modification includes a constant flow pump which draws directly from the head valve during washout.

[1] Obrist, W. D. et al. "Determination of Regional Cerebral Blood Flow by Inhalation of Xenon-133." Circulation Research, XX, 124-134, January, 1967.

PRICE LIST

Radx No.	Description	Price
101	Venti-Con Controlled Gas Delivery System	4915.00
102	Venti-Con Controlled Gas Delivery System with Strip Chart Recorder	5915.00

Both of the above units include the following:
- (1) 12" Flex tube with Adult Mouthpiece and headstrap. Please specify Adult Mouthpiece for Bolus Injection if desired.
- (1) Nose depressor
- (1) Quart of soda lime granules
- (1) 20' remote control cable
- (1) Installation and instruction manual

Radx No.	Description	Price
103	Single Channel Strip Chart Recorder	1,200.00
104	Soda Lime Granules — 1 Case (20 quarts/case)	40.00
105	Autoclavable Bacteriological Filter	35.00
106	Remote Control Cable — 20 feet	60.00
107	Chart Recorder Paper — 12 rolls (minimum)	180.00
108	Infant Mask (small, medium or large)	15.00
109	Adult Mouthpiece	15.00
110	Adult Face Mask	20.00
111	Adult Mouthpiece for Bolus Administration	30.00
112	Face Mask Tubing (12")	8.00
113	Face Mask Tubing (6")	6.00
114	Infant Face Mask Harness	8.00
115	Swivel Adaptor	25.00
116	Adult Face Mask Harness	8.00
127	Tubing — Interface Venti-Con/Xenon Trap	15.00
128	Tubing — exhaust port — per foot	.75
129	Expandable Interface	75.00
	Xenon-127 Additional lead shielding	200.00
	Cerebral Blood Flow Modification	400.00

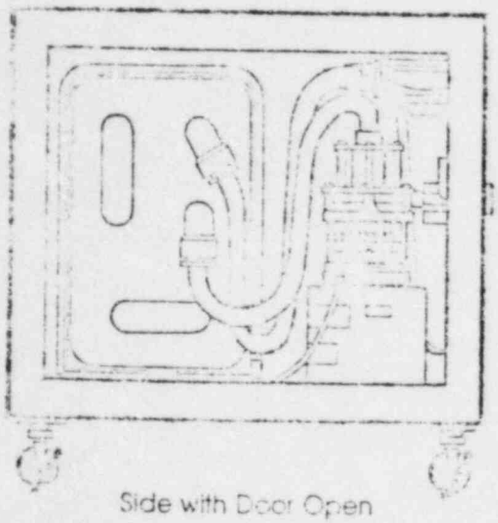
Terms: Net 30 days F.O.B. Houston, Texas
Prices effective August 1, 1976

Maintenance

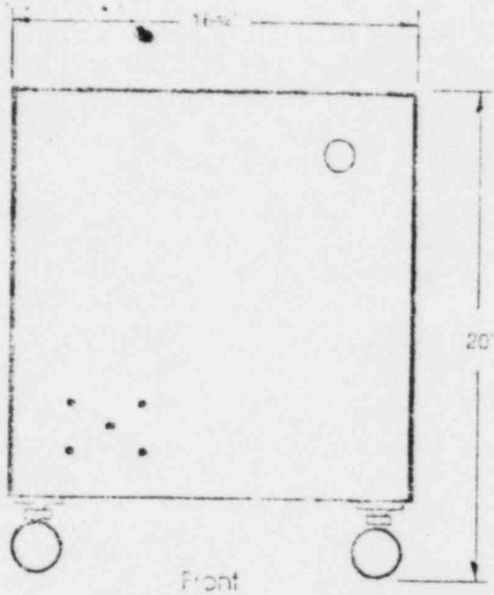
Routine cleaning and replacement of the soda lime granules is all the service your Venti-Con will require. Complete procedures for good care are outlined in the instruction manual.

RADX Warranty

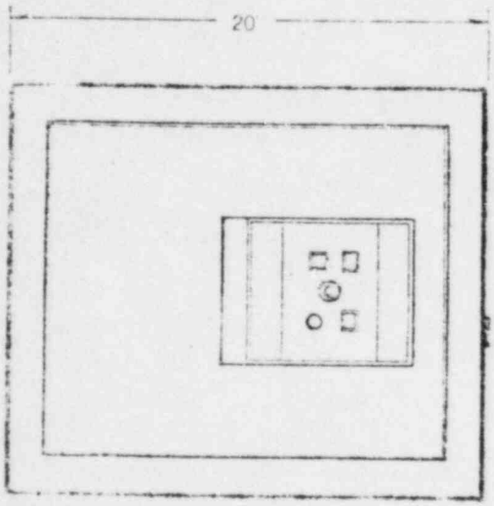
RADX warrants the Venti-Con to be free from all defective material and workmanship for a period of one year from date of shipment. RADX Corporation's liability shall be limited to the repair or replacement of the defective material or component at its option.



Side with Door Open



Front



Top

DESCRIPTION

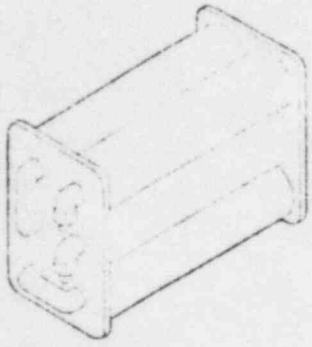
The RADX Xenon Trap was designed to economically and safely absorb radioactive xenon gas, primarily ^{133}Xe, as an effluent from patient washout in lung ventilation studies. The absorbent material is a special grade of activated charcoal, factory-filled into a sealed disposable cartridge pack. Total system absorption efficiency is better than 98% of the radioactive gas and under routine use conditions will last for many months.

The cartridge pack was designed for easy removal and replacement when it becomes saturated. After decay in storage the pack may be either reused or disposed of, depending on its residual absorption capacity. The entire cartridge pack storage area is lined with 3/16" lead which effectively shields large quantities of the very low energy gamma rays of ^{133}Xe.

Two models are available, one with and one without a GM detector. The detector constantly monitors the Xenon Trap exhaust port to warn when the cartridge pack has reached capacity. An audio "beeper" and visual red light warning system is built in to indicate immediately when the radiation level exceeds a pre-selected figure.

The electric motor of the circulation pump used to move the potentially oxygen enriched gaseous mixture through the charcoal trap is "flame isolated" from the flow. This feature eliminates the possibility of electric motor-induced combustion.

Product Specifications Price List



Cartridge pack – disposable pressure tested sealed unit with entrance and exit ports

Number of charcoal cylinders/cartridge pack – 6

Cartridge size – 3 1/2" x 12"

Cartridge pack life – use dependent

Lead shielding – 3/16"

Xenon detector (optional) – GM tube. Adjusted to activate alarm system when concentration of ^{133}Xe in the exhaust port reaches approximately 2×10^{-7} μCi/ml.

Warning system – Audio "beeper", visual red light. Warning system requires user action to deactivate.

Moisture trap – Heat reconstitutable silica gel desiccant

PRICE LIST

Radx No.	Description	Price
120	Xenon Trap with removable 6 cylinder cartridge pack, flame isolated circulation pump motor, 3/16" lead shielding and ^{133}Xe detector warning system	$1295.00
121	Xenon Trap with removable 6-cylinder cartridge pack, flame isolated circulation pump motor and 3/16" lead shielding (does not include ^{133}Xe detector warning system)	950.00
125	Cartridge Pack - 6-cylinder for No. 120 or No. 121 Xenon Trap	$225.00
126	Silica Gel Desiccant - 2 lbs.	15.00
127	Tubing - interface to Ventil-Con	15.00
128	Tubing - Exhaust Port per foot	.75
129	Expandable Interface	75.00

Terms: Net 30 days, F.O.B. Houston, Texas
Prices Effective October 1, 1976
Minimum order $25.00

Maintenance

Reconstitute the silica gel desiccant before it reaches saturation.

RADX Warranty

RADX Corporation warrants its products to be free from all defects in material and workmanship for a period of one year from the date of shipment. RADX Corporation liability shall be limited to the repair or replacement of the defective material at its option.