NRC FORM 313M
(9-81)
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB
3150-0041

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

Papastavros Associates, P.A.
Professional Building IV
Suite 100- Augustine Cut-Off
Wilmington, DElaware 19803

TELEPHONE NO.: AREA CODE (302) 652-3016

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Christos S. Papastavros, M.D.

TELEPHONE NO.: AREA CODE (302) 652-3016

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 07-16529-01

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

Garth A. Koniver, M.D.
Robert M. Kurtz, M.D.
Thomas W. Fiss, Jr., 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.)*

Garth A. Koniver, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

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

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	50
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 INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	40

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
Gadolinium-153	sealed source	2	Bone mineral analyzer

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. 1 Date: Oct. 1980

7. MEDICAL ISOTOPES COMMITTEE Not required	
	Names and Specialties Attached; and
	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE see attachment	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached

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

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Landauer	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Landauer	Monthly
		OTHER (Specify)		
c. WRIST	X	FILM	Landauer	Monthly
		TLD		
		OTHER (Specify)		

d. OTHER (Specify) Gamma III Radiation Monitor/Survey Meter - Range: 0-1 R with audible click (Atomic Products Corp. #052-999)

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)*

(1) LICENSE FEE CATEGORY: 7C

(2) LICENSE FEE ENCLOSED $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* C.S. Papastavros MD

(1) NAME *(Type of Print)* C.S. PAPASTAVROS M.D.

(2) TITLE PRESIDENT

c. DATE 4-10-85

NRC FORM 313M (9-81)

Garth A. Koniver, M.D.

Robert M. Kurtz, M.D.

Thomas W. Fiss, Jr., M.D.

Item: 8
Date: 3/27/85

18878

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Victoreen Instrument Division

   Manufacturer's model number: 492

   Number of instruments available: one

   Minimum range: zero mR/hr to 10 mR/hr

   Maximum range: zero mR/hr to 1000 mR/hr

   b. Manufacturer's name: Atomic Products

   Manufacturer's model number: EON PSM-700

   Number of instruments available: one

   Minimum range: zero mR/hr to 0.5 mR/hr

   Maximum range: zero mR/hr to 50 mR/hr

2. Dose calibrator

   Manufacturer's name: Capintec, Inc.

   Manufacturer's model number: CRC-17

   Number of instruments available: one

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Searle	Pho/Gamma IV
Gammma Camera	General Electric	Maxi-Camera 400
Uptake Probe	Ludlum Instruments	261

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

Area Monitor	Baird Atomic	441A
Xenon Gas Trap	Nuclear Associates	36-022
Velometer	Fischer Scientific Alnor Velometer	93-751

Item: #9
Date: 3/27/85

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

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

_____ 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

_____ a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

_____ (2) The calibration procedures in Section I of Appendix D will be used
or
_____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

X c. By a consultant or outside firm

(1) Name RAD Services, Inc. Pennsylvania **License No.** 37-17010-02

(2) Location 2045 Route 286, Pittsburgh, PA 15239

(3) Procedures and sources

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

X have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

X the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

_____ are described in the attachment, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

Item: #10
Date: 3/27/85

RAD Services Inc.

Number #TP-001
Revision #0
Date 12-10-82

RAD SERVICES
CONTROLLED COPY

RAD SERVICES, INC.

IRF Technical Procedure

Non-Routine Calibrations

Table of Effective Pages

Page	Date	Revision	Page	Date	Revision	Page	Date	Revision
1.0	12-10-82	0	26.0			51.0		
2.0	12-10-82	0	27.0			52.0		
3.0	12-10-82	0	28.0			53.0		
4.0			29.0			54.0		
5.0			30.0			55.0		
6.0			31.0			56.0		
7.0			32.0			57.0		
8.0			33.0			58.0		
9.0			34.0			59.0		
10.0			35.0			60.0		
11.0			36.0			61.0		
12.0			37.0			62.0		
13.0			38.0			63.0		
14.0			39.0			64.0		
15.0			40.0			65.0		
16.0			41.0			66.0		
17.0			42.0			67.0		
18.0			43.0			68.0		
19.0			44.0			69.0		
20.0			45.0			70.0		
21.0			46.0			71.0		
22.0			47.0			72.0		
23.0			48.0			73.0		
24.0			49.0			74.0		
25.0			50.0			75.0		

Director of Instrument Repair Facility Approval

Signature: Edward J. Mahoney Date: 12-16-82

ALARA Committee Approval

Signature: _____ Date: _____

Manager of Quality Assurance Approval

Signature: Patrick J. Francis Date: 12/20/82

Director of Instrument Services Approval

Signature: _____ Date: 12-17-82

TABLE OF CONTENTS

1.0 PURPOSE

1.1 The purpose of this procedure is to explain the steps that will be taken for all instruments that are received by RAD Services, for the purpose of calibration, that do not have a specific procedure of calibration.

1.2 The purpose also is to guarantee that these instruments are calibrated in accordance with the customer requirements, or the manufacturer's specifications.

2.0 SCOPE

This procedure covers all instruments received for the purpose of calibrations that do not have a procedure in accordance with RAD Services, Inc. Quality Assurance Procedure, QA-001 "IRF Procedure Format".

3.0 REFERENCES

3.1 RAD Services Quality Assurance Manual

3.2 RAD Services Procedure QA-001

4.0 RESPONSIBILITIES

4.1 It is the responsibility of the individual who performs the calibration to assure that the instrument is calibrated in accordance with the Instrument Manufacturer's Technical Manual, or the customer's specific request.

4.2 It is also the responsibility of the individual performing the calibration to assure that this information is recorded on the Calibration Certificate Form RS-23, under the comments section.

(In the event that any correction factors are needed in order to operate the instrument accurately, then this type of information must be affixed to the instrument, and noted under comments on form RS-23.)

Example: 1200 cpm = .5 MR/HR
based on ^{137}Cs

5.0 DEFINITIONS

N

6.0 PROCEDURE

6.1 Assure that the customer is aware that RAD Services does not have an approved procedure to calibrate the instrument in question.

This should be done by telephoning the customer and documenting the individual's name and date of conversation on form RS-23.

In cases where the customer has given written permission, a copy of this should be filed, along with the RAD Services copy of the calibration certificate form RS-23.

6.2 Under the section of "Instrument Information" of form RS-23, it should be noted that the calibration method was either manufacturer's specification, or customer's specification.

6.3 Complete the remaining sections of RS-23 and any other pertinent forms, such as RS-35 "Service Work Order", or any attachments to the Calibration Certificate to further clarify the calibration and work performed.

7.0 RECORDS

None

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FCMLB:MAL

JUL 3 1980

Rad Services, Inc.
ATTN: Edward J. Newbauer
Director of Instrument Services
3527 Whiskey Bottom Road
Laurel, MD 20810

Gentlemen:

This is to acknowledge receipt of your corporation's survey instrument calibration procedures. After carefully reviewing the information contained in the document, it appears that your corporation calibrates survey instruments in accordance with Regulatory Guide 10.8, Appendix B. Accordingly, your customers may reference your corporation rather than submitting detailed calibration procedures of their instruments.

If you have any questions or require clarification, you may contact us at (301)427-4232.

Sincerely,

Michael A. Lamastra
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

8008210197
1p.

Form RS-23
FD Rev 4/83

RAD Services Inc.

CALIBRATION CERTIFICATE

"This Certificate will be accompanied by Calibration Charts or Readings where applicable"

CUSTOMER INFORMATION

Customer Name: Radiology Associates
Customer Address: Suite 100, Prof. Bldg.
Augustine Cut-Off
Wilmington, DE 19803

Customer P.O.#
Service W.O.# I-85-03-205

INSTRUMENT INFORMATION

Instrument Manufacturer: Atomic Products
Model: EON Serial Number: 675116
External Probe(s): Serial #:
Calibration Method: ^{137}Cs s/n 107

INSTRUMENT CALIBRATION INFORMATION

	Instrument Range	Calibration Standard Value	Instrument Response Before Calib.	Instrument Response After Calib.	Comment
1	X1	0.1 mR/hr		0.1 mR/hr	All Calibrations Btn. + & - 10%
2		0.2		0.2	
3		0.4		0.4	
4					
5	X10	1		1	
6		2		2	
7		4		4	
8					
9	X100	10		10	
10		20		21	
11		40		44	
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					

STATEMENT OF CERTIFICATION

We Certify that the instrument listed above was calibrated and inspected prior to shipment and that it met all of the Manufacturers published operating specifications. We further certify that our Calibration Measurements are traceable to the National Bureau of Standards (We are not responsible for damage incurred during shipment or use of this instrument).

Instrument Calibrated by: Patricia A. Burch (Signed)
Calibration Date: 02-27-85
Next Calibration Due: 08-27-85

I certify that the above information is correct:
Authorized Agent: Theresa M Sparo
Title: Admin. Coordinator Date: 02-27-85

Item: #10
Date: 3/27/8

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

X First elution from new Mo-99/Tc-99m generator or maximum activity obtained from radio pharmacy

or

_____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

6-30-85

Radionuclide		Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	x*	3-5	0.96	4.3
Ba-133	x	0.1-0.5	0.176	
Cs-137	x	0.1-0.2	0.168	4 %
Ra-226		1-2		

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

or

X Equivalent procedures are attached.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

*Co-57 will be replaced before end of June 1985

Item: #10
Date: 3/27/85

Test of Instrument Linearity:

Instrument linearity test will be performed at time of installation and quarterly thereafter. The linearity test will be performed using a sample of Tc-99m containing an activity equivalent to the maximum activity employed in the laboratory (equivalent to a first elution from a new generator) or maximum obtained from a radiopharmacy company.

Linearity Test:

a. This will compare the actual and measured values of a sample of Tc-99m as it decays over several days (2 to 3). Calibrator readings in millicuries corrected for background will be plotted against elapsed time, in hours, on semi-log paper;

b. The calculated values, using the 24 hour activity as the starting point are also plotted and a straight line drawn;

c. If deviation of individual activity points from the calculated straight line does not exceed 5 percent, linearity of the dose calibrator is shown;

d. In conjunction with this linearity test, appropriate measurement of the cobalt-57 standard will be made at least once on each day of the test and logged along with the Tc-99m readings.

Item: #10
Date: 3/27/85

Test for Instrument Accuracy:

The accuracy of the dose calibrator will be determined by using Cs-137, Co-57, and Ba-113 whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS. Documentation is contained in the Calibration Certificate issued with each source.

The three reference standards will be used to test for instrument accuracy at installation and annually thereafter, and after repair or adjustment.

The following procedure will be used to test for instrument accuracy:

1. The reference standards will be assayed in the dose calibrator at the appropriate instrument settings, background activity will be subtracted to obtain the net activity. This procedure will be repeated for all three reference standards and three readings will be made for each reference source in order to calculate average net activity.

2. The average measured net activity of the reference sources will be compared with decay corrected listed activity of the reference sources. Deviations of greater than 5 percent will require repair or adjustment of the dose calibrator.

3. After the dose calibrator has been tested for accuracy, the Cs-137 will be used to obtain readings for all radionuclides used at this facility. These readings will be recorded in instrument log-book, along with calibration test results.

Test for Instrument Constancy:

The three reference sources will be assayed daily using the appropriate instrument setting at the start of each working day. The measured activity will be adjusted for background activity and compared with decay adjusted listed activity of the reference sources. Differences greater than 5 percent will indicate need of repair or adjustment of the dose calibrator.

Monthly

The Cs-137 source will be used to obtain readings for all radionuclides used at this facility. These readings will be compared with reading obtained at time test for instrument accuracy was determined. Deviations greater than 5 percent between these readings will indicate need for repair or adjustment of the dose calibrator.

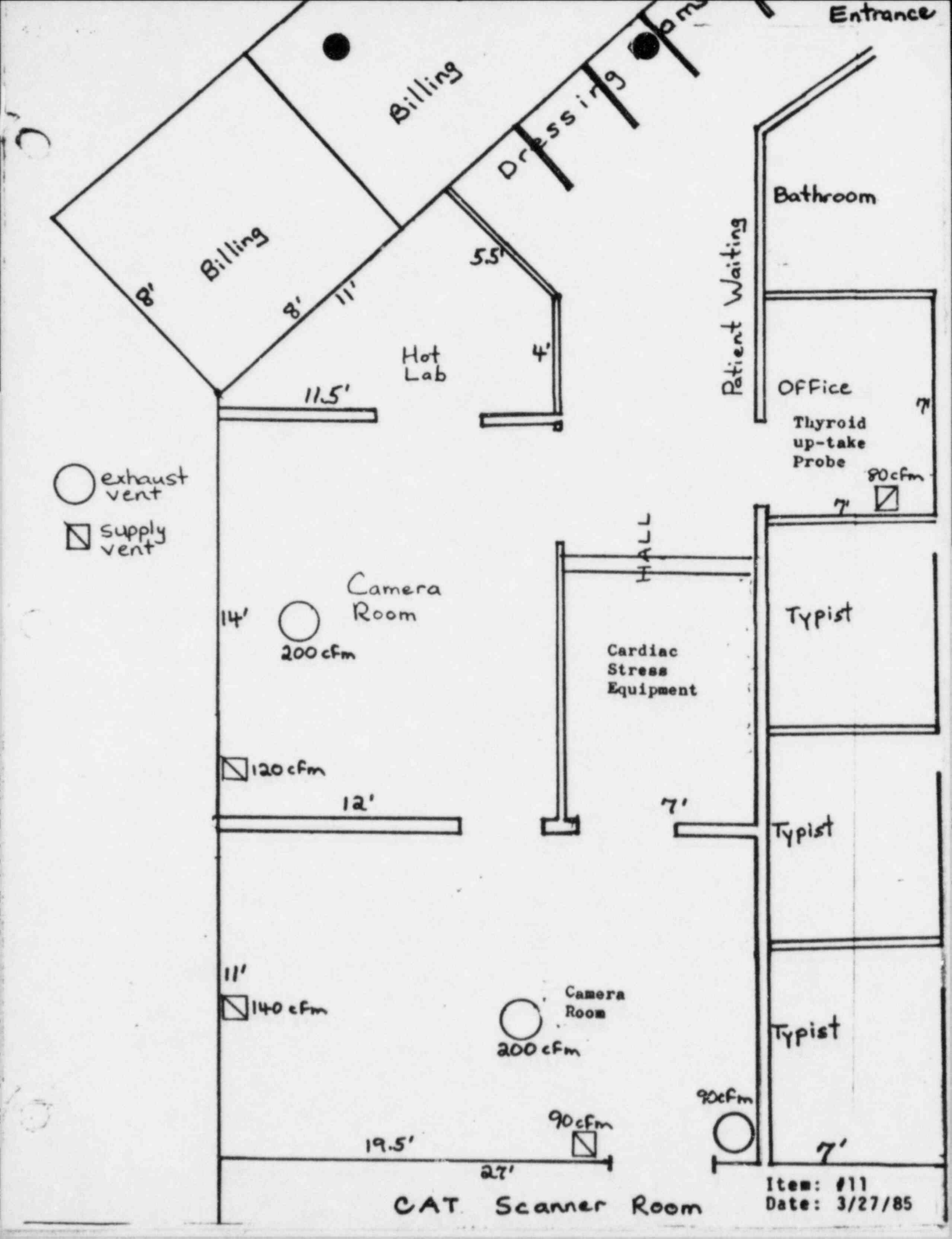
Item: #10
Date: 3/27/85

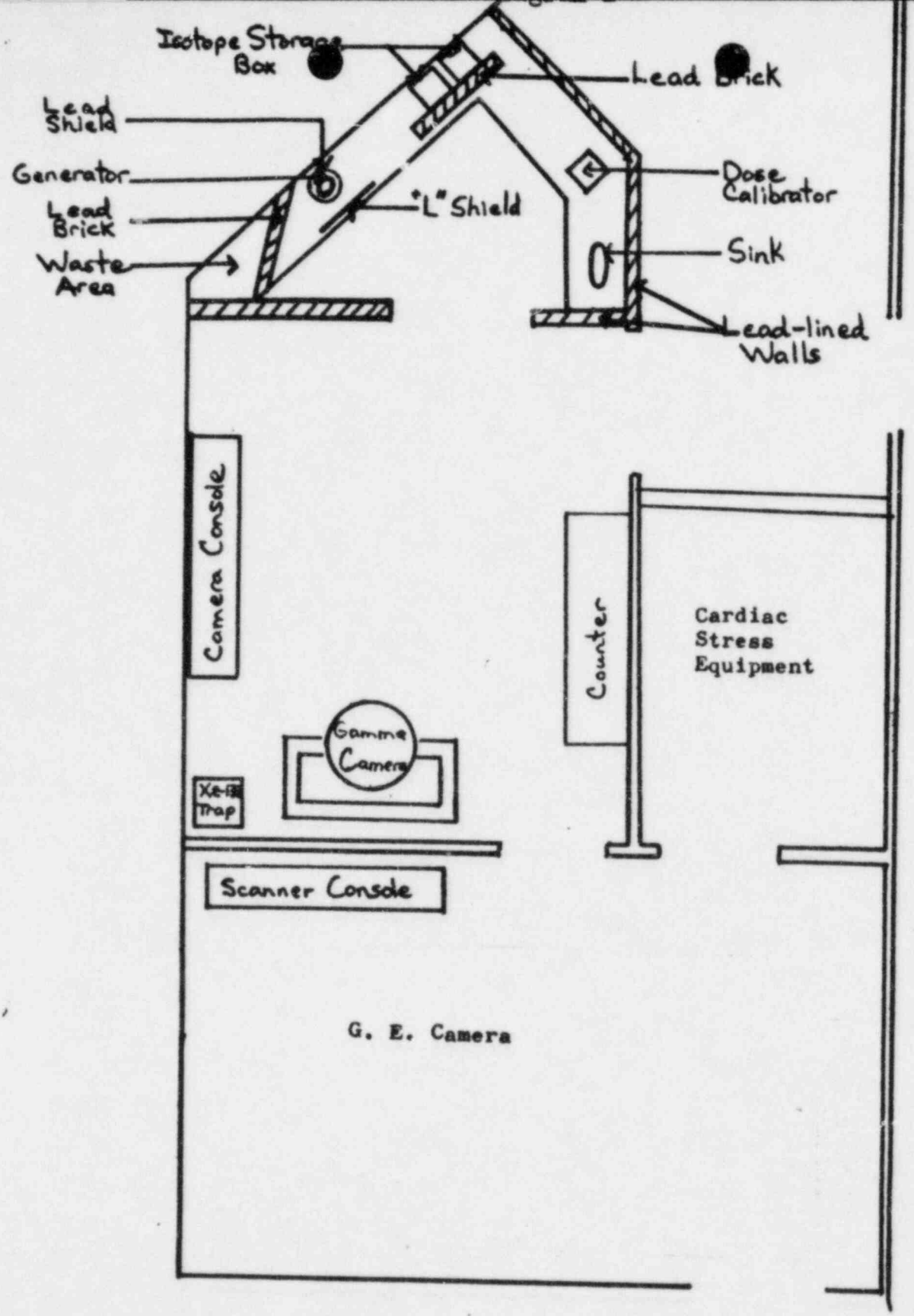
Facilities and Equipment

The Nuclear Medicine Section has three rooms dedicated to work with radioactive materials. There are two separate imaging rooms and a storage-handling room ("hot lab"). The "hot lab" is lined on its two inner walls and ceiling with approximately .5mm lead. Additional shielding, waste and storage areas, generator location, airflow rates, etc. are detailed on the enclosed diagrams (Diagram 1 & 2). The air from the G.E. Camera room's 90 cfm exhaust is recirculated.

Additional equipment provided to maintain personnel doses ALARA include; syringe shields, syringe holders, long-handled tongs, rolls of absorbent paper, Tc-99m elution vial and generator shields.

Item: #11
Date: 3/27/85


Entrance
Billing
Billing
Billing
Dressing
Bathroom
Patient Waiting
8'
8'
11'
5.5'
4'
Hot Lab
11.5'
OFFice
7'
Thyroid up-take Probe
80cfm
7'
exhaust vent
supply vent
Camera Room
14'
200 cfm
WALL
Typist
Cardiac Stress Equipment
120 cfm
12'
7'
Typist
11'
140 cfm
Camera Room
200 cfm
Typist
90cfm
90cfm
19.5'
27'
7'
CAT Scanner Room
Item: #11
Date: 3/27/85



Item: # 11
Date: 3/27/85

Personnel Training Program

All personnel, especially those who would be expected to enter the restricted area of the Nuclear Medicine Department, will receive instructions relative to the potential hazards of exposure to radioactive materials. These individuals will receive instructions before assuming duties and after any change in duties or requirements of the license. Refresher training will be provided as required. Instructional programs will be based on the specifications of Section 19.12 of 10CFR Part 19 and will include:

a. areas where radioactive material is used or stored;

b. biological effects associated with radioactive material;

c. radiation safety and emergency procedures;

d. rules and regulations of the NRC and our license;

e. the prompt reporting of any condition which may cause or lead to a violation of NRC regulations;

f. the availability of radiation exposure reports and location of pertinent notices and information.

Training will consist of discussion sessions and handout materials covering the attached information.

Item:#12
Date: 3/27/85

Procedures for Ordering and Receiving Radioactive Material

All orders for radioactive materials are placed by the Nuclear Medicine Technologist to ensure that the materials and quantities are authorized by the NRC license.

Arrangements have been made with radionuclide suppliers to deliver shipments during the normal work week when possible. If deliveries are made during off-duty hours, the packages are delivered to the "ambulance entrance" vestibule which is kept locked during all off-duty hours. In this case, the Nuclear Medicine Technologist checks the vestibule for delivered materials at the start of each working day.

All shipments shall be handled according to.10CFR20.205. All radionuclides used by this facility fall into Transport Groups III, IV, or VI and, under no circumstances, will we be ordering activities in excess of Type A activity limits.

The above procedures are adequate to ensure radioactive materials are secure against unauthorized removal and that radiation levels in unrestricted areas do not exceed the limits specified in 10CFR20.105.

Item: #13
Date: 3/27/85

Receiving and Opening Radioactive Packages

Upon receipt, all packages containing radioactive materials are brought directly to the Nuclear Medicine Laboratory and placed immediately in the Hot Lab. It is essential that packages be opened as soon as possible following receipt.

Wear plastic gloves during the opening procedure.

1. Check exposure rate at the package surface with the Victoreen 492 and/or EON PSM G-M survey meters. Exposure rates at the surface in excess of 200 mr/hr may be indicative of loss of containment. If this occurs, DO NOT OPEN PACKAGE- notify the RSO immediately;

2. Open outer package, remove packing slip.....open inner package and verify that all contents agree as to type and activity with the listing on the packing slip;

3. Check inner containers for seal breakage, obvious loss of liquid, evidence of absorption of liquid on inner surfaces of package. If such evidence exists, notify RSO prior to proceeding. Special handling may be required;

4. If shipment appears intact, remove active material from package and place immediately behind lead shielding. Record each nuclide received, along with date, chemical form, amount of activity and name of supplier on Receiving Log (attached).

5. With the G-M survey meter, check the empty package and inner lining material for evidence of residual activity and record this activity in the log. Do not discard any packing material in regular trash until this has been done. If there is any evidence of contamination, packing materials must be held as "hot" waste for decay or disposal by commercial service. On uncontaminated packaging materials, make every effort to remove or deface labels indicating presence of radioactivity, prior to disposal through regular channels;

6. All active material received must be stored only in the location designated. Record must be made of its receipt. Any discrepancies in quantity or type, any loss of containment and any contamination of packing material must be reported to the RSO immediately, as shipper and supplier may need to be informed.

Item: #14
Date: 3/27/85

PAPASTAVROS ASSOCIATES, P. A.
SUITE 100
THE PROFESSIONAL BUILDING IV
AUGUSTINE CUT-OFF
WILMINGTON, DELAWARE 19803

Christos S. Papastavros, M.D.
John S. Plendak, M.D.
John W. Alden, M.D.

Robert M. Kurtz, M.D.
Garth A. Koniver, M.D.

NUCLEAR MEDICINE PACKAGE MONITORING BOOK

Date	Company	Radionuclide	Reading		Initials
			Outside	Inside	

Item: # 14
Date: 3/27/85

NM-7-7/78

18878

Storage of Radioactive Materials

All radioactive materials must be stored in the following designated areas:

1. The molybdenum-technetium generator system is stored in a lead shield behind the lead-glass barrier on the work area.

2. Radiopharmaceuticals that must be refrigerated are stored in the refrigerator in the "hot lab" area in protective lead containers that are properly labelled with isotope, date and activity.

3. All other radioactive materials are stored in protective lead containers, appropriately labelled, in the radioisotope storage container.

4. All radioactive waste must be stored in the shielded waste storage area.

Item:#14
Date: 3/27/85

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. 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 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

Item 17

Item: #15
Date: 3/27/85

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

1. **NOTIFY:** Notify persons in the area that a spill has occurred.

2. **PREVENT THE SPREAD:** Cover the spill with absorbent paper.

3. **CLEAN UP:** Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. **SURVEY:** With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. **REPORT:** Report incident to the Radiation Safety Officer.

Major Spills

1. **CLEAR THE AREA:** Notify all persons not involved in the spill to vacate the room.

2. **PREVENT THE SPREAD:** Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. **SHIELD THE SOURCE:** If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. **CLOSE THE ROOM:** Leave the room and lock the door(s) to prevent entry.

5. **CALL FOR HELP:** Notify the Radiation Safety Officer immediately.

6. **PERSONNEL DECONTAMINATION:** Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: G.Koniver *
OFFICE PHONE: 652-3016
HOME PHONE: 655-5388

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

Christos S.Papastavros, M.D.
652-3016
658-0576

* The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

Item 16

Item: #16
Date: 3/27/85

Area Survey Procedures

1. The areas used for elution of Mo-99/Tc-99m generators, for preparation of radiopharmaceuticals from reagent kits, and for preparation of individual patient doses will be surveyed daily with the G-M survey meter. Records of survey results will be kept on the attached form (attachment 1).

2. Weekly surveys of radiation levels and removable contamination levels will be performed in the "hot lab", camera and scanner rooms. Records of survey results will be kept on the attached forms (attachments 1 & 2). Survey areas are keyed to the attached diagram.

3. All wipes will be counted using the Ludlum Spectrometer Model 261 at the appropriate setting for the radionuclide of concern. The wipes will cover an area of 100 square centimeters. The counting time will be selected so that minimum sensitivity shall exceed 2000 dpm per 100 sqare cm.

4. Areas showing ?0,000 dpm per 100 square centimeters will be considered contaminated and will be decontaminated if possible.

5. Laboratory areas (except "hot lab") giving G-M readings over .05 mr/hr (200 cpm) shall be considered contaminated and must be decontaminated with the necessary follow-up surveys.

Item #17
Date: 3/27/85

Christos S. Papastavros, M.D.
John S. Plendak, M.D.
John W. Alden, M.D.

PAPASTAVROS ASSOCIATES, P. A.
SUITE 100
THE PROFESSIONAL BUILDING IV
AUGUSTINE CUT-OFF
WILMINGTON, DELAWARE 19803

Robert M. Kurtz, M.D.
Garth A. Koniver, M.D.

DEPARTMENT MONITORING

Date	Instrument	Area	Reading	Initials	Date	Instrument	Area	Reading	Initials

Item: #17
Date: 3/27/85

HM-8-7/79

PAPASTAVROS ASSOCIATES, P. A.
SUITE 100
THE PROFESSIONAL BUILDING IV
AUGUSTINE CUT-OFF
WILMINGTON, DELAWARE 19803

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John S. Plandak, M.D.
John W. Alden, M.D.

Robert M. Kurtz, M.D.
Garth A. Koniver, M.D.

WIPE TEST

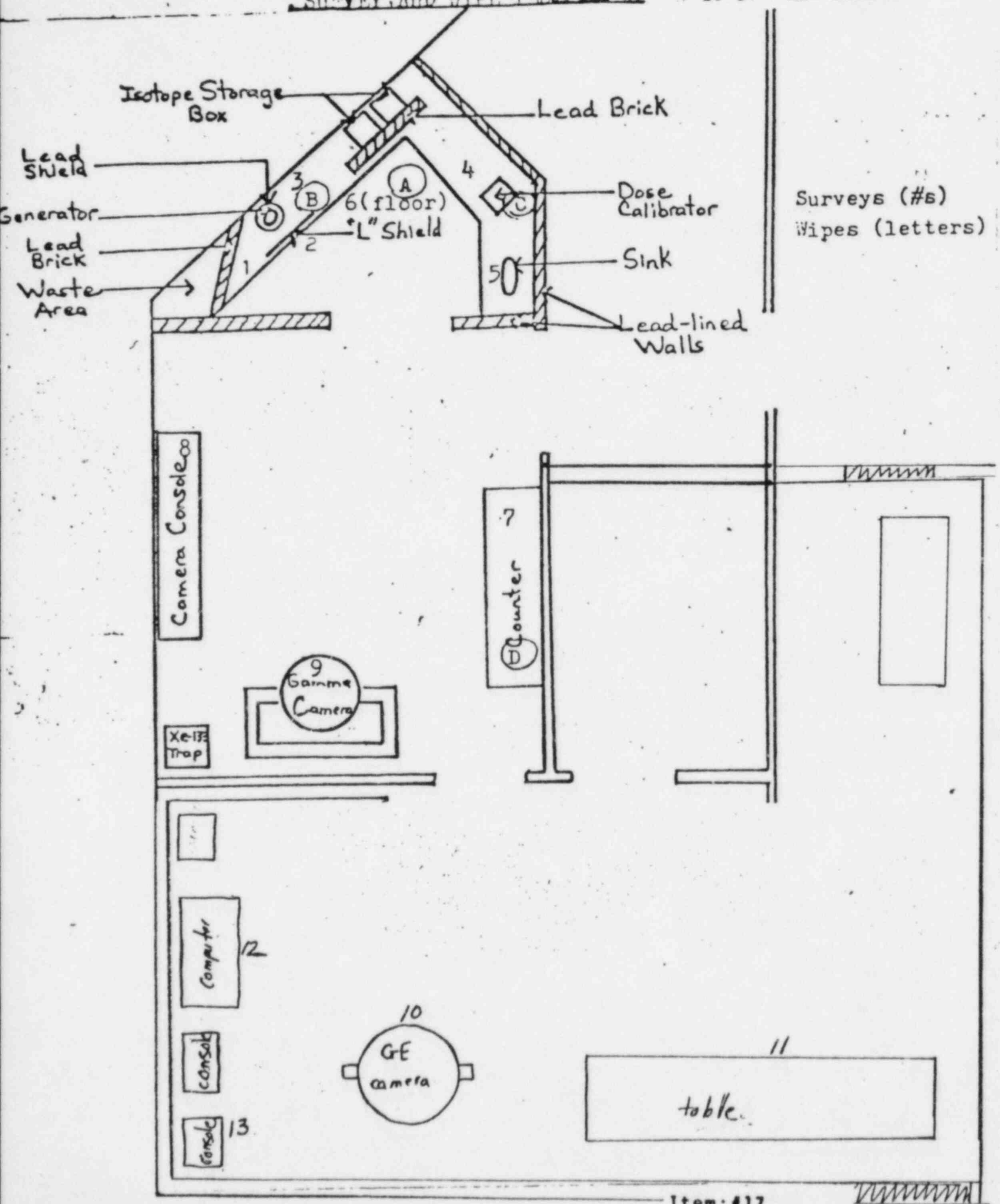
Date	Area	Window	Lower Level	Bkg.	Counts (μCi) Per Min.	Initials

Item: #17
Date: 3/27/85

NM-8-7/79

Contamination

SURVEY AND WIPE TEST AREAS



Item: #17
Date: 3/27/85

Waste Disposal

We are currently acquiring all our radiopharmaceuticals from Mallinckrodt, Inc. located in Philadelphia, Pennsylvania. All unused radiopharmaceuticals are returned to Mallinckrodt. The only radioactive trash retained under our control consists of syringes used to administer the radiopharmaceuticals, and the alcohol wipes used to wipe injection site. This trash is held for decay until radiation levels, as measured in a low background area with a low level survey meter are at background levels.

Any Mo-99/Tc-99m generators that we acquire will be returned to the manufacturer for disposal. In this regard, new warning labels are affixed to the packages. These labels contain the following information: radionuclide,number of curies and transport index (if applicable). A wipe test will be made on the exterior surface of the boxes to insure that they are free of "significant removable contamination" (less than 2.2×10^4 dmp/100 cm^2).

Our current method of disposing of radioactive trash is to return it to the company that we acquired it from or, if that is not possible, retain it until it decays down to background levels and then discard it as non-radioactive trash.

Item: #18
Date: 3/27/85

Therapeutic Use of Radiopharmaceuticals

Therapeutic procedures are limited solely to Iodine-131 as iodide for the treatment of hyperthyroidism. The dosage for such treatment will be up to 10 mCi per treatment.

The Iodine-131 will be stored in its lead shipping container in the "hot lab" storage area. Safety, handling and emergency procedures have been detailed in items 12, 13, 14, 15 and 16 of this application.

Bioassays will not be required since Iodine-131 capsules will be employed for all treatments.

Item: #19
Date: 3/27/85

Procedures and Precautions for
the Use of Xenon-133

1. A possession limit of 40 mCi of Xenon-133 is requested. An average of 1 patient study per week, using 10 mCi per patient will be performed.

2. The Xenon-133 will be stored in the "hot lab" area (Diagram 2) in its lead shipping container in the lead lined storage boxes. The Xenon-133 will be administered and the patients imaged in the camera imaging room where an 8.5" exhaust fan is located on the ceiling above the camera. An adjoining room also contains an 8.5" exhaust fan. There are no windows located in these areas but there is a door to the outside at the end of the patient dressing and waiting area (Diagram 1). The exhaust from the two 8.5" fans is exhausted to the outside and not recirculated into the building air supply. The volume of the camera room where the Xenon-133 will be used is approximately 1344 cubic feet. The location of supply and exhaust vents is detailed in Diagram 1. The air from the second exhaust located in the G.E. camera room is recirculated.

3. All doses for patient use will be checked immediately prior to administration with the Capintec Model Number CRC-17 Dose Calibrator. All personnel working in Nuclear Medicine use whole body film badges and finger ring TLD's.

4. The radiation safety procedures and survey equipment are the same as those described in items 9 and 15 of this application.

5. The Xenon-133 will be supplied by Mallinckrodt,Inc. in single dose vials of approximately 10 mCi each.

6. The equipment that will be used for the studies are the Searle Pho/Gamma IV Camera, Nuclear Associates Model 36-022 Xenon Gas Trap, and Atomic Products No. 060-133 Xenon-133 Rebreathing System as well as the "Calidose Dispenser Delivery System" provided by New England Nuclear Corporation.

7. Since the "hot lab" is directly off the camera room and does not have a separate exhaust, the two are considered together for Xenon-133 release calculations. The maximum concentration of Xenon-133 for 40 hours in seven consecutive days for this restricted area is calculated to be:

$$C = \frac{Af}{V}$$

$A = 1 \times 10^{4}$ uCi/wk

$f = 0.25$

$V = 200$ cfm $= 1.36 \times 10^{10} \frac{ml}{wt}$

$C = 1.9 \times 10^{-7}$ uCi/ml

Item: #21
Date: 3/27/85

8. In the event of an accidental release of several stored patient doses, the following procedure will be implemented: the fan in the scanner room will be activated, all personnel will leave the area and all doors to unrestricted areas will be closed. The area will remain unoccupied for 15 minutes. The area will then be surveyed with the G-M survey meter to insure that the radiation levels have returned to normal for the area. A volume of air equal to more than fifteen times the area's capacity will be exchanged in 15 minutes.

9. Air Concentration in Unrestricted Areas

Maximum number of patients per year = 20

$C = \frac{A\ f}{V}$

$A = 200$ mCu/year

$f = 0.25$

$V = 2.97 \times 10^{12}$ ml/yr

$C = 1.7 \times 10^{-8}$ uCi/ml

10. The Xenon-133 gas will be used in the following manner: The patient will be instructed on the details of the procedure. Before the study is attempted with the Xenon-133 gas, one or more practice runs will be made with the patient. The unit dose will be measured on the dose calibrator and loaded into the Calidose Dispenser system in the "hot lab". It will then be taken to the camera room for use with the Xenon delivery system. Nose clamps will be used to prevent the patient from exhaling the Xenon-133 into the room. After the study is completed the used Xenon-133 gas will be exhausted into the "Nonex" gas trap.

11. The operational status of the charcoal trap will be tested after each patient using the following method:

    a. A polyethylene bag will be placed over the exhaust part of the "Nonex" trap system.

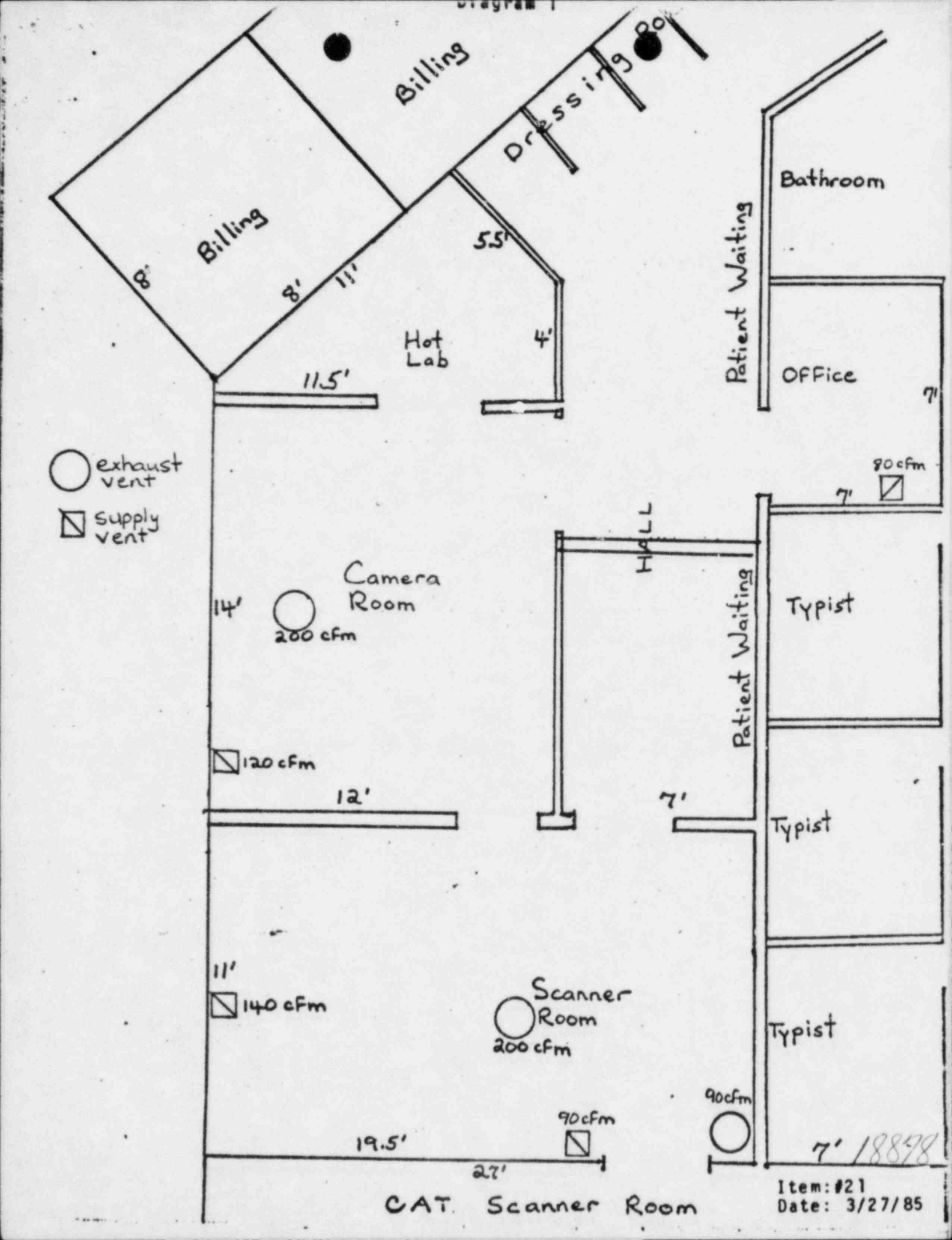
    b. The unit will be operated until the bag is full.

    c. The bag will be sealed and counted for one minute on the Searle Gamma Camera.

    The counts will be recorded and compared with previous and baseline readings. The cartridge will be replaced when the cpm indicates that the maximum permissible concentration for a controlled area is being approached. The saturated cartridge will be stored in the "Hot lab" until decay permits disposal as non-radioactive trash, i.e., approximately 60 days after removal from patient use

12. The manufacturer's operating and maintenance instructions will be followed for all equipment used in the ventilation studies.

Item: #21
Date: 3/27/85


Billing
Billing
Dressing
8'
8'
11'
5.5'
4'
Hot Lab
11.5'
Bathroom
Patient Waiting
Office
7'
exhaust vent
supply vent
80 cfm
7'
HALL
Camera Room
14'
200 cfm
Patient Waiting
Typist
120 cfm
12'
7'
Typist
11'
140 cfm
Scanner Room
200 cfm
Typist
90 cfm
90 cfm
19.5'
27'
7'
CAT Scanner Room
Item: #21
Date: 3/27/85

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

Regional License Section
Material Licensing Branch
FCMS, Office of Nuclear Material
Safety & Safeguards

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Papastavros Associates, P.A.

Application Dated: 4/10/85

Control No.: 018878

License No.: 07-16529-01

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed _____

Date _____

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 Frances Brown

Date 4/17/85

4/19/85