NRC FORM 313M (8-86) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE -- MEDICAL**	Approved by OMB 3150-0041 Expires 6-30-89

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

Charleston Area Medical Center
P.O. BOX 1547
Charleston, WV 25326

TELEPHONE NO.: AREA CODE( ) _____

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

See Page A-2

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Ridgely G. Conant

TELEPHONE NO.: AREA CODE (304) 348 4252

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

a. ☐ NEW LICENSE
b. ■ AMENDMENT TO LICENSE NO. 47-15473-01
c. ☐ RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)* Individual users are appointed by the Radiation Safety Committee (formerly the Medical Isotopes Committee) per previous license #47-15473-01. See page A-3.

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.)*

Ridgely G. Conant
See pages 5 and A-1

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE.

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	3 each
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	6,000
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	1,000

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 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	300

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

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Americium - 241	Sealed source	14	See page A-4
Cesium - 137	Sealed source	100	See pages A-5 thru A-11
Iodine - 131 Iodomethyl-19-Norcholesterol (NP-59)		200	See pages A-12 thru A-15
Gadolinium-- 153	Sealed Source	3,000	Dual photon bone densitometry See page A-95

8801120105 870630
REG2 LIC30
47-15473-01 PDR

NRC FORM 313M (8-86)

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

- [X] Names and Specialties Attached; and See page A-3
- [X] Duties as in Appendix B; or *(Check One)*
- [ ] Equivalent Duties Attached

8. TRAINING AND EXPERIENCE

- [ ] Supplements A & B Attached for Each Individual User; and
- [X] Supplement A Attached for RSO. See page 5 and pages A-1 and A-3

9. INSTRUMENTATION *(Check One)*

- [ ] Appendix C Form Attached; or
- [X] List by Name and Model Number See pages A-16 to A-24

10. CALIBRATION OF INSTRUMENTS

- [ ] Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
- [X] Equivalent Procedures Attached; and See page A-25
- [ ] Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
- [X] Equivalent Procedures Attached See page A-25

11. FACILITIES AND EQUIPMENT

- [X] Description and Diagram Attached See pages A-26 to A-44

12. PERSONNEL TRAINING PROGRAM

- [X] Description of Training Attached See page A-45

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

- [X] Detailed Information Attached See pages A-46 and A-47

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*

- [ ] Appendix F Procedures Followed; or
- [X] Equivalent Procedures Attached See page A-48

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*

- [ ] Appendix G Rules Followed; or
- [X] Equivalent Rules Attached See pages A-49 thru A-51

16. EMERGENCY PROCEDURES *(Check One)*

- [X] Appendix H Procedures Followed; or See page A-52
- [ ] Equivalent Procedures Attached

17. AREA SURVEY PROCEDURES *(Check One)*

- [ ] Appendix I Procedures Followed; or
- [X] Equivalent Procedures Attached See page A-53

18. WASTE DISPOSAL *(Check One)*

- [ ] Appendix J Form Attached; or
- [X] Equivalent Information Attached See pages A-54 thru A-59

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*

- [ ] Appendix K Procedures Followed; or
- [X] Equivalent Procedures Attached See pages A-60 thru A-67

20. THERAPEUTIC USE OF SEALED SOURCES

- [X] Detailed Information Attached; and See pages A-68 thru A-84
- [ ] Appendix L Procedures Followed; or *(Check One)*
- [X] Equivalent Procedures Attached See pages A-68 thru A-84

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)

- [X] Detailed Information Attached See pages A-85 thru A-94

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

- [ ] Detailed Information Attached

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

- [X] Detailed Information Attached See page A-96

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		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Log
Receipt
Check No.
Amount
Fee Category
Type
Date
Date Acknowledged
By

June - 3 - II
43765
$120
TC
Amd
6/5/87
6/8/87
Mussier

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: License fee previously forwarded to Region II Atlanta office and received there as per telephone conversation this date. RGC

(2) LICENSE FEE ENCLOSED: $

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* + Robert L Savage

(1) NAME *(Type or Print)* Robert L Savage

(2) TITLE Senior Vice President

c. DATE 5-27-87

NRC FORM 313M (9-81)

PRIVACY ACT STATEMENT

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

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

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

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

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

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

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME [redacted] RADIATION SAFETY OFFICER Ridgely G. Conant	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE NOT APPLICABLE

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Registry of Radiologic Technologists	Nuclear Medicine	November, 1971
Nuclear Medicine Technology Certification Board	Nuclear Medicine	January, 1980

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	NNMC, Bethesda, Maryland	103	507
b. RADIATION PROTECTION	NNMC, Bethesda, Maryland	38	32
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	NNMC, Bethesda, Maryland	38	30
d. RADIATION BIOLOGY	NNMC, Bethesda, Maryland	40	--
e. RADIOPHARMACEUTICAL CHEMISTRY	NNMC, Bethesda, Maryland	87	44

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

The hours of training related in the listed subject matter areas of section 4 on the reverse side of this form are part of a successfully completed 1,700 contact hour program conducted at the National Naval Medical Center, Bethesda, Maryland in Clinical Nuclear Medicine Technology. This program also included 16 contact hours specifically covering Therapy Procedures inclusive of both radionuclide therapies and brachytherapies.

In addition to the successful completion of this program, this applicant became an instructor and taught these specifically listed (in section 4) subject matter areas. From January, 1972 to January, 1977 each below course was taught to the number of classes indicated.

Radiation Physics	1
Radiation Instrumentation	11
Radiation Biology	10
Radiation Protection	3
Chemistry	7
Radiopharmaceuticals	2

From January, 1977 to June, 1980 these subject matter areas were again taught by this applicant on at least two additional occasions each.

On-the-job experience is as listed below:

November, 1971 to January, 1977	National Naval Medical Center Bethesda, Maryland	11,000 hrs.
November, 1971 to February, 1976	Prince George's General Hosp. Cheverly, Maryland	5,500 hrs.
January, 1977 to June, 1980	Nuclear Medicine Institute Mayfield Heights, Ohio	7,000 hrs.
July, 1980 to present	Charleston Area Medical Center Memorial Division, Charleston, WV	14,000 hrs.

This applicant's experience has included a wide variety of radionuclides including C-14, F-18, P-32, Cr-51, Co-57, Fe-59, Co-60, Ga-67, Se-75, Kr-81m, Sr-85, Mo-99, Tc-99m, In-111, I-123, I-125, Xe-127, I-131, Xe-133, Cs-137 (as sealed calibration source and brachytherapy sources), Gd-153 (as sealed source), Yb-169, Au-198, Tl-201, Ra-226 (as sealed brachytherapy sources), and Am-241 (as low-level sealed source). Also, this applicant's most recent past position and current position include administrative responsibilities which contained radiation safety policies, programs, practices, and performance.

Thus, it is felt this applicant's training, position, experience and knowledge qualify him as Radiation Safety Officer and support his ability to effectively perform the position's duties.

Item 1.b.

used at	3200 MacCorkle Avenue, S.E. Charleston, WV 25304
used at	Brooks & Elmwood Streets Charleston, WV 25325
used at	800 Pennsulvania Avenue Charleston, WV 25302
stored at	1300 Lee Street Charleston, WV 25325

The addition of the Pennsulvania Avenue address is a transfer of activities currently licensed by license number 47-17747-01. These activities are to henceforth be conducted in accordance with this license, number 47-15473-01, as a result of a corporate merger of the two currently separately licensed facilities.

Upon receipt of this amended license #47-15473-01, license #47-17747-01 will be terminated.

RADIATION SAFETY COMMITTEE MEMBERS

Ridgely G. Conant, CNMT
Radiation Safety Officer

Robert E. Smith, Chairman
American Board of Radiology
American Board of Nuclear Medicine

Steven A. Artz, M.D.
American Board of Nuclear Medicine

Mary B. Taylor, M.D.
American Board of Pathology
Director of Blood Bank, CAMC

Ernesto R. Tanguilig, M.D.
American Board of Radiology

Edward R. Wheatley, M.D.
American Board of Radiology

James J. Wente
Associate Administrator, Memorial Division, CAMC

Rachael Byrd, R.N.
Assistant Director of Nursing, Memorial Division, CAMC

Supplements A & B of individual users approved by the Radiation Safety Committee are on file. Criteria for authorization by the Radiation Safety Committee are as promulgated in Appendix A of Regulatory Guide 10.8. Additionally future users will be considered eligible for selection only if American Board of Radiology with Special Competence in Nuclear Medicine and/or American Board of Nuclear Medicine criteria have been fulfilled.

The Radiation Safety Officer is assisted in his duties by a consultant, Health Physics Services, Inc., 4 Research Place, Suite 140, Rockville, Maryland, 20850. Applicable duties of the consultant include surveys of radioactive material handling/storage areas, at least every six months, review of records of ongoing surveys, review of occupational worker personnel monitoring reports, provide occupational worker continuing education, leak testing of sealed sources at least every six months, calibration and response testing of radiation protection instrumentation at least every six months, provide data regarding changes to regulations and recommendations, and miscellaneous services as required. It is estimated these services require 24 man-hours/month.

The purpose of this inclusion in Item 6.b. is to delete Americium-241 from the radioactive materials this facility is licensed to acquire, possess, store, and use. The licensed Am-241 was an imaging (anatomical) marker which was an accessory of and was affixed to a Siemen's LFOV Scintillation Camera.

This imaging camera was replaced. Thus, possession and ownership of the unit changed. Along with this change and the unit's relocation was, of course, the relocation of the Am-241 marker. Therefore, this Am-241 sealed source was transferred to

Iso-Graphics
4660 N. Royal Atlanta Dr.
Tucker, GA 30084

and transferred to agreement state radioactive materials license # GA499-1.

Therefore, it is requested that this Am-241 be excluded from this license #47-15473-01.

J. L. SHEPHERD and Associates

NEW ADDRESS:
740 Salem St.
P. O. Box 4337
Glendale, CA 91202

703 So. Pacific Avenue, Glendale, California 91204 • 213/245 0187

Irradiation Equipment • *Counting Systems* • *Nuclear Applications*

CERTIFICATION

EXTERNAL RADIATION LEVELS

TO: Charleston Area Medical Center

Device: Series 10 Beam Calibrator S. N. 550

Source in "OFF" position:

≤ 1.0 mR/hr at 1 foot from the surface

Source in "ON" position:

N. A.

/Date: June 24, 1976

J. L. Shepherd

NEW ADDRESS:
740 Salem St.
P. O. Box 4337
Glendale, CA 91202

To: Charleston Area Medical Center

010439

Source: 100 mCi. ^{137}Cs CS 2-4 S. N. 74-167

Model: Series 10 Beam Calibrator

Instrument: Landsverk Model L-64 Roentgen Meter S. N. 438

Free Air	Centered in Beam Port
1.00 meter	1.00 meter
37.6 mR/hr	33.6 mR/hr

June 24, 1976

NEW ADDRESS:
740 Salem St.
P. O. Box 4337
Glendale, CA 91202

Charleston Area Medical Center

100 mCi. ^{137}Cs CS 2-4 S. N. 74-167

≤ 0.00015 microcuries

June 24, 1976

J. L. SHEPHERD and Associates
703 South Pacific Avenue
P.O. Box 4337 Glendale, CA 91202
213 245-0187

WE'RE MOVING

as of July 1, 1976

to a new manufacturing facility
and corporate headquarters

located at

740 Salem, Glendale, California
P.O. Box 4337

Our telephone number will remain unchanged

(213) 245-0187

You are cordially invited to visit our booth at the annual Health Physics Society Meeting, June 27 - July 2, 1976, at San Francisco Hilton Hotel. We will have a complete range of working models of calibration facilities and irradiators manufactured by J. L. Shepherd and Associates available for your inspection, including:

MARK I Model 68 self-contained ^{137}Cs irradiator

Model 143-34 self-contained ^{137}Cs irradiator

Model 78-2M complete with Model 154 attenuator system and Model 89 shielded calibration range

Model 78-2M dual source calibrator, complete with model 150 track system

Model 81 remotely operated calibrator/irradiator

Series 10 portable calibrator

Model 149 neutron calibration facility

MARK IV TLDosimeter calibrator (two models)

Model 179 neutron howitzer

Various models of portable instrumentation

We look forward to seeing you there.

Sincerely,

J. L. Shepherd

SERIES 10 PORTABLE BEAM

CALIBRATORS WITH REMOVABLE SOURCES

Model 10 are lightweight, portable Calibration Facilities designed for the calibration of low or intermediate range survey meters, as well as remote area monitor probes or other applications in which it is desirable to use a small gamma source with attached handler for panoramic or free air exposures.

These units include a 100mCi ^{137}Cs gamma source mounted on the end of a shielded plug, which fits into an NRC/DOT approved shipping and storage container. A handler, which threads into the shielded end of this plug, is supplied so that the source may be removed from the shield for panoramic exposures. A second removable plug is provided in line with the source, which may be removed to provide a 20° beam port for the calibration of survey instruments.

These shields are equipped with handles so that they may be easily transported. Weight is only 40 pounds.

An 18 inch handler is provided for manipulation of the source in free air exposures.

All sources are calibrated free air with an accuracy of ±5% with Bureau of Standards traceable Roentgen Meters.

SPECIFICATIONS

External radiation level is 5 mR/hr or less at one foot from the surface.

All beam port plugs as well as source rods are equipped with padlocks for storage.

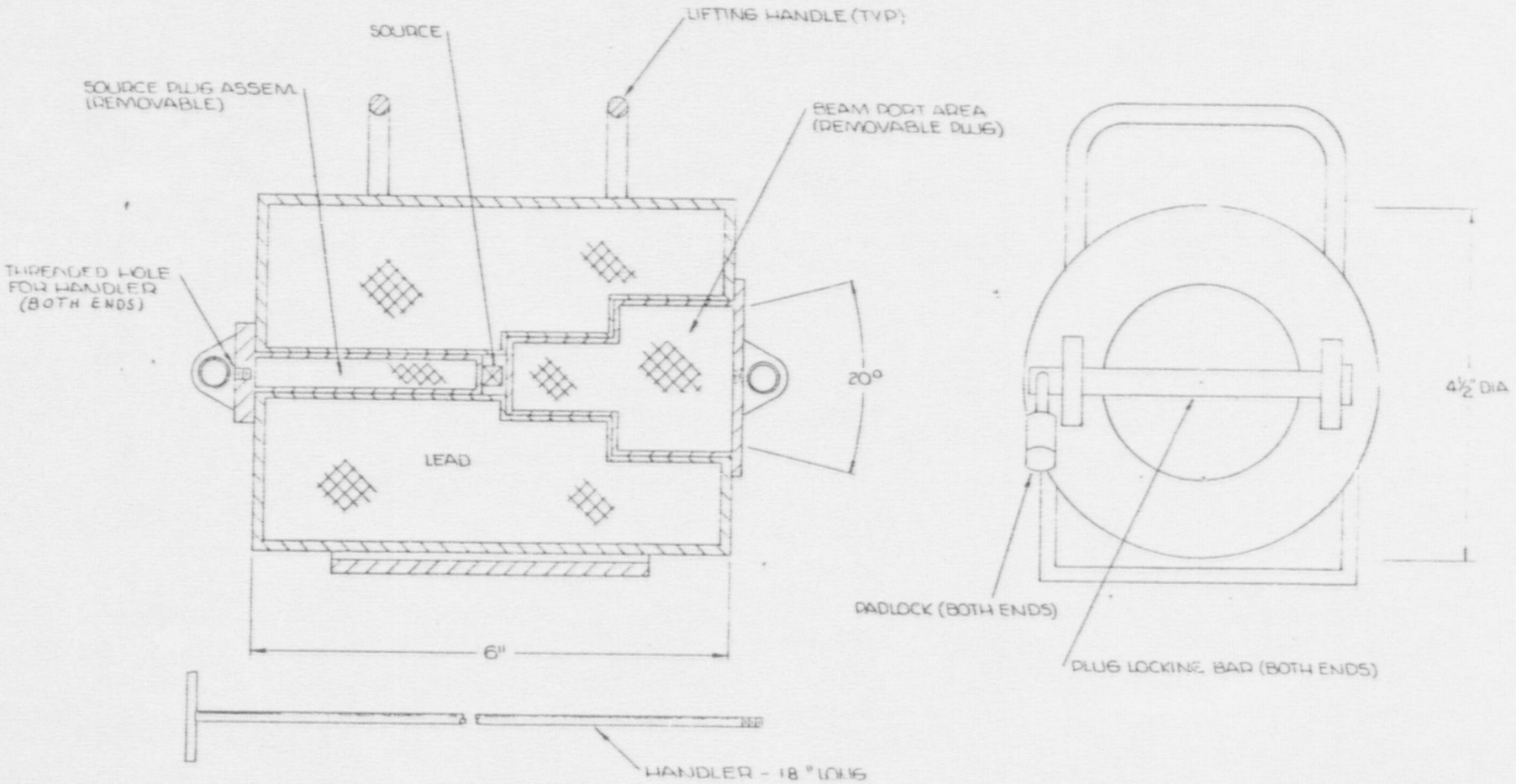
Carrying handle and storage tube for handler are built in.

Source	100 mCi ^{137}Cs "Special Form"			
Output	6"	12"	20"	40"
	1400 mR/hr	350 mR/hr	128 mR/hr	32 mR/hr
Handler	18" long			
Weight	40 pounds			
Dimensions	Shield	4½" dia. x 6" long		
	Overall	4½" side x 10" long x 10" high		
Price	$645.00			

Model 10-A with 50 mCi. ^{137}Cs source. Weight 32 lbs. Otherwise identical to Model 10. Price $595.00.

JL SHEPHERD and Associates
703 S. Pacific Avenue
Glendale, California 91204
213 245-0187

NEW ADDRESS
740 Salem
P. O. Box
Glendale, C



NOTE

1. ALL WELDED STEEL CONSTR.
2. SURFACES INSIDE/OUTSIDE FINISH PER JLS SPEC
3. WEIGHT - 40 LBS.

J. L. SHEPHERD and Associate		
SCALE FULL	APPROVED BY	DRAWN BY
DATE 6-1-73		REV NO
BEAM CALIBRATOR WITH REMOVABLE SOURCE		
PROPOSAL		DRAWING NUMBER A 0306

The Cs-137 calibration source is kept behind two doors, which are locked in the absence of authorized personnel, in the storage area illustrated on page A-35. The calibration source housing also has a lock which is secured when the source is not in use. The key to this lock is kept separate from the device in the Nuclear Medicine Department. This source is no longer used. Thus, it is included solely for the purposes of authorized and appropriate possession and storage. It will not be used. If it would be decided to again use this source in the future, this would be coordinated through the Nuclear Regulatory Commission via appropriate ammendment to this license and any other activities required at that time.

As per ammendment 16 of the current license #47-15473-01, the inclusion of 131 Iodine Iodomethyl-19-Norcholesterol (NP-59) remains included as one of the radiopharmaceuticals the use of which is requested within this license renewal application.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

IND 17,095

MAR 6 1980

Steven A. Artz, M.D.
P.O. Box 1393
Charleston, West Virginia 25325

Dear Dr. Artz:

We acknowledge receipt of your Notice of Claimed Investigational Exemption for a New Drug (IND) submitted pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act. Please note the following identifying data:

IND Number Assigned: 17,095

Sponsor: Steven A. Artz, M.D.

Name of Drug: I-131-6-B-Iodomethyl-19-Norcholesterol (NP-59)

Date of Submission: January 2, 1980

Date of Receipt: January 7, 1980

As sponsor of the clinical study proposed in this IND you are now free to obtain supplies of the investigational drug, but it is understood that studies in humans will not be initiated prior to 30 days after the date of receipt shown above. If, within the 30 day period, we notify you of serious deficiencies which require correction before human studies can begin or which require restriction of human studies until correction, it is understood that you will continue to withhold or restrict such studies until you are notified that the material you have submitted to correct the deficiencies is satisfactory.

You are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and Regulations. This includes the immediate reporting of any alarming reactions in either animal or human studies, and submission of progress reports at intervals not to exceed one year.

All future communications concerning this IND should be forwarded in triplicate, identified with the IND number assigned, and addressed as follows:

Bureau of Drugs HFD-150
Attention: DOCUMENT CONTROL ROOM 17B-34
5600 Fishers Lane
Rockville, Maryland 20857

Sincerely yours,

William J. Gyarfas

William J. Gyarfas, M.D.
Director
Division of Oncology and
Radiopharmaceutical Drug Products
Bureau of Drugs

NRC Form 374A (8-82) U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 1 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
47-15473-01
Docket or Reference number

Amendment No. 16

Charleston Area Medical Center
Post Office Box 1547
Charleston, West Virginia 25326

In accordance with letter dated December 9, 1992, License Number 47-15473-01 is amended as follows:

Sublitem 9.A. is amended to read:

9.A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations. Use of Iodine 131, Iodomethyl-19-Norcholesterol (NP-59) in accordance with IND 17,045.

Condition 20. is added:

20. The licensee shall notify the U.S. Nuclear Regulatory Commission within thirty days of the termination of any "Notice of Claimed Investigational Exemption for a New Drug" (IND) cited in Item 9 above.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date _____

By William J. Walker, Jr.
Material Licensing Branch
Division of Fuel Cycle and
Material Safety
Washington, D. C. 20555

INSTRUMENTATION

AT

3200 MacCorkle Ave., S.E.
Charleston, West Virginia
25304

INSTRUMENTATION

1. SURVEY METERS

A. Manufacturers Name: Picker
Manufacturers Model Number: 655-186
Number of instruments available: 1
Minimum range .01 mR/hr to .2 mR/hr
Maximum range 100 mR/hr to 2000 mR/hr

B. Manufacturers Name: Eberline
Manufacturers Model Number: E 120
Number of instruments available: 1
Minimum range .1 mR/hr to .5 mR/hr
Maximum range 10 mR/hr to 50 mr/hr

C. Manufacturers Name: Eberline
Manufacturers Model Number: 130 A
Number of instrumants available: 1
Minimum range 1 mR/hr to 10 mR/hr
Maximum range 100 mR/hr to 1000 mR/hr

D. Manufactures Name: Victoreen
Manufactureres Model Number: 6 A
Number of instruments available: 1
Minimum range .1 mR/hr to .5 mR/hr
Maximum range 10 mR/hr to 50 mR/hr

2. DOSE CALIBRATORS

Number of instruments available: 2
Manufacturers Name: Capintec
Manufacturers Model Number: CRC-30

Manufacturers Name: Capintec
Manufacturers Model Number: CRC-4

3. INSTRUMENTS USED FOR DIAGNOSTIC PROCEDURES

Type of Instrument	Manufacturers Name	Model #
Spectroscaler 3A	Picker	Ser # 16094
Spectroscaler 4R/Probe	Picker	628438/Ser # 1342
Promeda MCA	Elscint	Ser # 41603606
MCA	Canberra Series 35	3201
Scaler, power supply	Harshaw	Ser # 403948
Quality Graph	ADC	QG-100
Well	Gamma Products	G4-W
Well	Picker	Ser # 163
Gamma Camera	Technicare	414
Gamma Camera	Technicare	438
Gamma Camera, Portable	Technicare	420
Computer System	Technicare	450
Computer System	Technicare	560
ECG Gate	Technicare	150-12
ECG Patient Monitor, Graph	General Electric	46-203462G1A
ECG Gate	American Optical	Ser# 001358
A^2Computer MultiTerminal	Medical Data System	Ser# 00310 Mod.$A^2$40

Ergometer	Collins	Ser # 1448
Computer System	Technicare	560
Centrifuge	American Scientific	122126
A Computer Multi-Terminal	Medical Data System	
Lab Monitor	Picker	642081
Lab Monitor	Picker	642081
Ibrinitor	Searle	92731-150
Xenogard	Nuclear Associates	36-751 Ser# 14570
Nonex Xenon Gas Trap	Nuclear Associates	Cat # 36-022
XDS Senon Delivery System	Nuclear Associates	Cat # 36-103
Kodak Film Processor	Kodak	M-6B
Printer	Texas Instruments	Ser# 04711-80772
Video Imager	Matrix Instruments	1000
Exercise Bike	Schwinn	8AL2019R
Stress Table	Nuclear Associates	17-571
Video Imager	Matrix Instruments	1000
Spect Camera	Elscint	409
Spect Camera	Elscint	415
Defibrillator	Physio-Control	Lifepak 6
Xenon System Pulmonex	Atomic Products	130-527

INSTRUMENTATION

AT

Brooks & Elmwood Streets
Charleston, West Virginia
25325

CHARLESTON AREA MEDICAL CENTER
GENERAL DIVISION
NUCLEAR MEDICINE DEPARTMENT
INSTRUMENTATION

1. Survey Meters

a.	Manufacturer's name:	Victoreen
	Manufacturer's model number:	#491
	Number of instruments available:	One
	Range:	(0-100) X 0.1 - X 100 mR/hr
b.	Manufacturer's name:	Eberline
	Manufacturer's model number:	#E 120 E
	Number of instruments available:	One
	Range:	0 - 50k mR/hr
c.	Manufacturer's name:	Victoreen - Cutie Pie
	Manufacturer's model number:	#740 B and #740 F
	Number of instruments available:	Two
	Range:	(0-25) X 1 - X 100 mR/hr

2. Dose Calibrator

Manufacturer's name:	Capintec
Manufacturer's model number:	#CRC 17
Number of instruments available:	One

INSTRUMENTATION
(continued)

3. Instruments used for diagnostic procedures

Type	Manufacturer's Name	Model Number
Gamma Well Counter	Picker	#630085
Gamma Auto Well II Counter	Picker	#640005
Gamma Well Counter	Micromedic	#4/200+MACC+ADD
Gamma Well Counter	Nuclear Medical Laboratories	NML 5000
Dyna Camera	Ohio Nuclear	RC 100
Dyna Camera	Raytheon Medical Systems	Step I/II
Dyna Camera	Raytheon Medical Systems	Step I/II
Scaler & Probe	Picker	#2801-D, #4R
Data System	Ohio Nuclear	Series 160
Computers 2	ADAC	CDS 303
Ultimat	Ohio Nuclear	#100
Autowell II	Picker	#16481
Spectroscaler 4-R	Picker	#628438
Programmable Automatic Calculator	Picker	#OPT1,7

4. Other

Liquid Scintillation - Beta	Packard	#2425
Lab Monitor	Picker	#642081
Two Pocket Dosimeters	Nuclear Associates	#702230 #702206
Ibrinator	Searle	#290

INSTRUMENTATION
(continued)

Nonex Xenon Gas Trap	Nuclear Associates	#36-022
XDS Xenon Delivery System	Nuclear Associates	Cat. #36102
Q. C. Analyzer	Squibb	#QC-10

INSTRUMENTATION

AT

800 Pennsylvania Avenue
Charleston, West Virginia 25302

A- (1) Victoreen Survey Meter - CDV - 700 Model 6 B

(2) Victoreen Survey Meter - CDV - 715 Model 1 A

B- Capintec Dose Calibrator - Model CRC 6 A

C- Technicare Wide Field of View Gamma Camera - Sigma 410

Abbott Auto-Logic Gamma Counter

D- Lunar model DP3 Dual Photon Bone Densitometer

CALIBRATION OF SURVEY METER INSTRUMENTATION

Survey meter calibrations will be conducted on a quarterly basis by Health Physics Services, Inc., Potomac, Maryland, using sealed Cesium-137 sources of approximately 500 mCi, authorized by the State of Maryland under License Number MD-31-035-01. The calibration procedures are on file with the NRC, under License No. 19-19791-01.

DOSE CALIBRATOR CALIBRATION AND LINEARITY PROCEDURES

1. On a daily basis, the constancy of the dose calibrator will be determined with two sources: 200uCi of Cesium-137, and greater than one millicurie of Cobalt-57. These sources are NBS traceable with an accuracy of ±5%. Should the error of the constancy measurement be greater than ±5%, appropriate adjustment or instrument repair will be affected.

2. On a quarterly basis, Health Physics Services, Inc., Potomac, Maryland, will conduct the dose calibrator calibrations under Maryland License Number MD-31-035-01.
   A Cobalt-57 source of approximately 10 millicuries will be used to insure the dose calibrator accuracy. Should the calibration deviate by greater than ±5%, appropriate adjustment or instrument repair will be conducted. This quarterly procedure will be repeated using a Cesium-137 and a Barium-133 source of approximately 0.2 millicuries each. The three calibration sources are NBS traceable with an accuracy of ±5%.

3. The linearity of the dose calibrator will be determined quarterly by Health Physics Services, Inc., or Charleston Area Medical Center, in accordance with the NRC Medical Licensing Guide, Appendix D, Section 2.E., over the full range of activities of Technetium used. Should the linearity (measured versus calculated) vary by greater than ±5%, appropriate corrective action will be conducted.

4. Test for geometrical variation will be conducted in accordance with Appendix D, Section 2, Item F., of the NRC Medical Licensing Guide, unless certified data is supplied by the dose calibrator manufacturer.

CALIBRATION OF DIAGNOSTIC INSTRUMENTATION

Calibrations of diagnostic instrumentation, to include gamma cameras and associated instrumentation will be conducted in accordance with the manufacturers' instructions.

Daily floods will be conducted to insure integrity of the camera.

LEAK TESTING OF SEALED SOURCES

On a semi-annual basis, all sealed sources of radioactive material will be leak tested by Health Physics Services, Inc., in accordance with their Maryland license, No. MD-31-035-01.

Radiation Handling Equipment

To enable personnel to work safely with unsealed radioactive materials, the Nuclear Medicine Departments have proper radiation handling equipment. The following is a list of basic radiation handling equipment which is available:

Tongs

1	9"
1	9½"
1	9 3/4"
1	11½"
1	17"
1	18"

Syringe Shields

8	¼"Pb
8	½"Pb
2	3cc Lead Glass
1	6cc Lead Glass
5	3cc 1/8" Pb
1	5cc 1/8" Pb
1	1cc 1/8" Pb
1	10cc 1/8" Pb

Vial Shields

56	3/8"	Pb	10cc
5	¼"	Pb	30cc
1	¼"	Pb	10cc
1	½"	Pb	10cc

Elution Vials

5	3/8"	Pb	30 cc

Dose Carriers

5	1/8" Pb	Inside Diameter: 2¼" x 7 5/8" x 2¼"

Lead bricks
Laboratory coats
Absorbant pads
Disposable gloves
Decontaminating agents
Caution signs and labels
"L-block" personnel shields
Cs-137 Therapy source safe
Cs-137 Therapy source carrier

FACILITIES

AT

3200 MacCorkle Ave., S.E.
Charleston, West Virginia 25304

CHARLESTON AREA MEDICAL CENTER

3200 MacCorkle Avenue, S. E. • Charleston, West Virginia 25304 • P.O. Box 4396
304/348-5432

November 13, 1986

To: Radiation Safety Committee

Subj: Nuclear Medicine Department Final Survey

On Wednesday, November 12, 1986 after cessation of Nuclear Medicine activities and the handling of all radiopharmaceuticals in the department illustrated on the following page, these illustrated spaces which are located at the address on page A-27 were thoroughly monitored for any signs of radioactive contamination. This monitoring was via survey with with a low-level survey meter and wipe test.

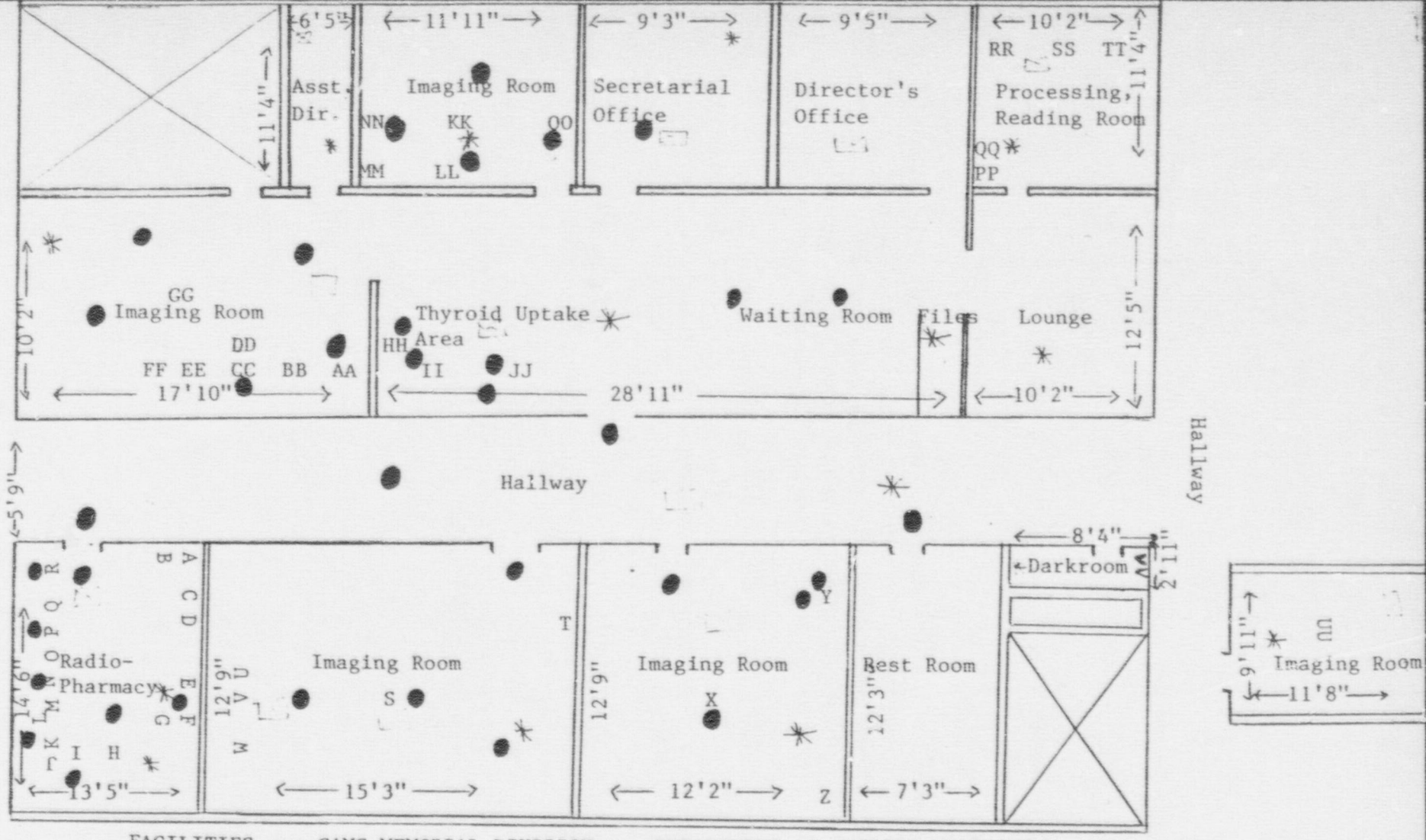
Virtually the entire area was evaluated with the survey meter with emphasis on all horizontal surfaces including the floor. This emphasis entailed thorough surveying to the degree that any point on any horizontal surface came within 2 feet of the G-M probe during the survey. No exposure levels in excess of 0.2 mR/hr. were observed.

Wipe tests were performed at 36 locations throughout the Nuclear Medicine area. These locations are illustrated and listed on the following pages. All wipe tests demonstrated counts which were less than 100 dpm above background.

Thus, no evidence of radioactive contamination was found. The spaces were able to be normally available to personnel as unrestricted areas.

Respectfully forwarded,

Ridgely G. Conant
Director, Nuclear Medicine



A-29

FACILITIES - - CAMC MEMORIAL DIVISION - - DEPARTMENT OF NUCLEAR MEDICINE

A. Picker Spectroscaler III A
B. Survey Meters
C. Elscint Promeda
D. Picker Well
E. Gamma Products Well
F. Canberra Series 35 MCA
G. Harshaw scaler,power supply
H. Laminar Flow Hood with L-Block
I. Capintec CRC-30
J. Capintec CRC-4
K. Lead Storage Drawers
L. Exhaust Hood
M. L-Block Shield
N. ADC Qualitygraph
O. Refrigerator
P. Sink
Q. Picker Lab Monitor
R. Generator Storage
S. Pho/Con Imaging Unit
T. A^2 Terminal
U. Pho/Con Console
V. Microdot Imager
W. Lead Storage for Flood Sources
X. Technicare 438 Console
Y. Technicare 150 Data System
Z. Technicare 438 Imaging Unit
AA. H/P EKG Monitor
BB. Technicare 560
CC. Technicare 414 Console
DD. A^2 Terminal
EE. G.E. Ekg Monitor & Graph
FF. Technicare ECG Gate
GG. Technicare 414 Camera
HH. Picker Thyroid Probe
II. Picker Spectroscaler 4R
JJ. Amersham Ibrinitor
KK. Searle LFOV Cemera
LL. A^2 Terminal
MM. Searle Microdot

NN. Searle LFOV Console
OO. Xenon Trap and Delivery System
PP. A^2 CPU
QQ. Matrix Imager
RR. Technicare 450
SS. A^2 Terminal
TT. Printer
UU. Technicare Mobile 420
VV. Kodak Film Processor

✱ Exhaust
⊠ Air Conditioning

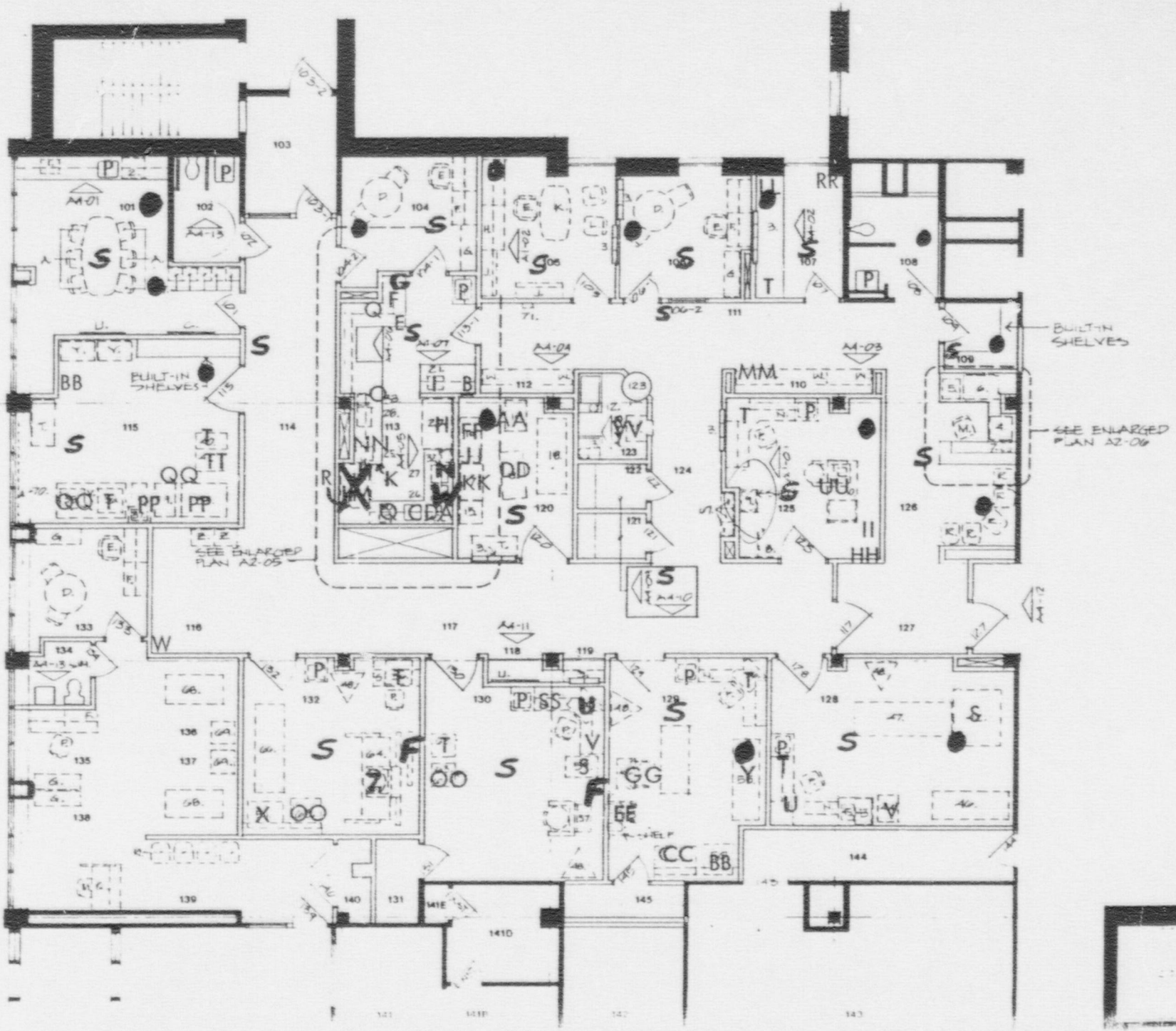
● Wipe test locations

WIPE TEST LOCATIONS

Generator storage area in the Nuclear Pharmacy
Nuclear Pharmacy sink
Quality Control/work area
Counter-top beneath exhaust hood
Dose calibrator work area
Nuclear Pharmacy formulation/work area
Two locations of the Nuclear Pharmacy floor
SPECT imaging room floor at patient table area
SPECT imaging room at technologist work station counter top
Two additional floor locations in the SPECT imaging room
Area Scan imaging room floor at patient table area
Camera counter top in the Area Scan imaging room
Floor near camera console in Area Scan imaging room
Area Scan imaging room floor at door
Two floor locations in patient waiting room
One floor location in secretary office
Table top technologist work area in LFOV imaging room
Floor at patient table area in LFOV imaging room
Camera console counter top in LFOV imaging room
One additional floor location in LFOV imaging room
Patient stressing area in Cardiac imaging room
Camera console counter top in Cardiac imaging room
Cardiac imaging room floor at patient imaging table area
Two additional floor locations in the Cardiac imaging room
Thyroid uptake patient table
The floor at the thyroid uptake patient table
Thyroid uptake counter top work area
The floor at the thyroid uptake counter top work area
Four locations along main departmental hallway

ROOM IDENTIFICATION

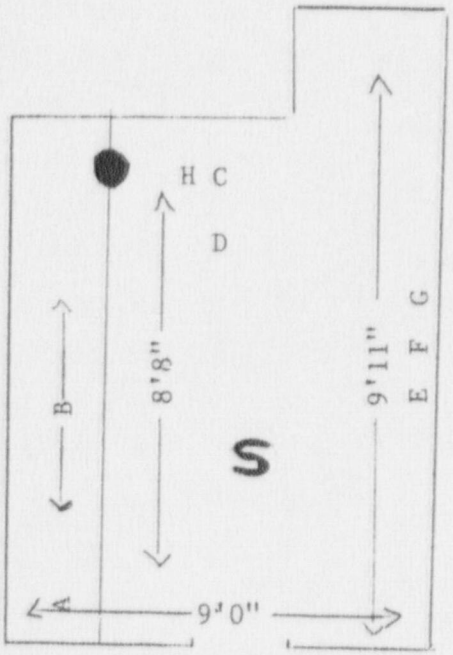
101 - Conference Room/Lounge
102 - Restroom
103 - Exit
104 - Pharmacist's Office
105 - Director's Office
106 - Ass't. Director's Office
107 - Reading Room
108 - Restroom
109 - Storage
113 - Nuclear Pharmacy
114 - Hallway
115 - Computer Room
116 - Patient Holding
117 - Hallway
118 - Organizer's Station
120 - Dosing/Stressing/Examination Room
121 - Dressing Room
122 - Dressing Room
123 - Darkroom
124 - Hallway
125 - Imaging Room/Mobile Camera
126 - Reception/Patient Waiting
128 - Imaging Room
129 - Imaging Room
130 - Imaging Room
131 - Storage
132 - Imaging Room
144 - Hallway
145 - Electrical Room
143 - Telephone Equipment Room142
142 - Electrical Equipment/Storage
141 - All (141, 141B, and 141D) are Hospital Information personnel work areas


BUILT-IN SHELVES
SEE ENLARGED PLAN A2-05
SEE ENLARGED PLAN A2-06
BUILT-IN SHELVES
A4-01
A4-02
A4-03
A4-04
A4-05
A4-07
A4-11
A4-12
A4-13
A4-15
A4-16
RR
A-33

FACILITIES-CAMC MEMORIAL DIVISION-DEPARTMENT OF NUCLEAR MEDICINE

A. Picker Spectroscaler III A.
B. Survey Meters
C. Elscint Promeda
D. Picker Well
E. Gamma Products Well
F. Canberra Series 35 MCA
G. Harshaw scales power supply
H. Laminar Flow Hood with L-Block
I. Capintec CRC-30
J. Capintec CRC-4
K. Lead Storage Drawers
L. Exhaust Hood X
M. L-Block Shield
N. ADC Qualitygraph
O. Refrigerator
P. Sink
Q. Picker Lab Monitor
R. Generator Storage
S. SPECT Imaging Unit
T. A-Terminal
U. SPECT Console
V. SPECT Computer
W. Lead Storage for Flood Sources
X. Technicare 438 Console
Y. Stress Table
Z. Technicare 438 Imaging Unit

AA. Quinton EKG Monitor
BB. Technicare 560
CC. Technicare 414 Console
DD. Stress Bike
EE. EKG monitor and Graph
FF. "Crash" Cart
GG. Technicare 414 Camera
HH. Picker Thyroid Probe
II. Picker spectroscaler 4R
JJ. Amersham Ibrinitor
KK. Defibrillator
LL. IBM PC
MM. Copier
NN. Centrifuge
OO. Xenon Trap and Delivery System
PP. A^2 CPU
QQ. Matrix Imager
RR. Technicare 450
SS. Imager
TT. Printer
UU. Technicare Mobile 420
VV. Kodak Film Processor
● Exhaust ceiling
S Air Conditioning
W Wall exhaust at counter
F Wall exhaust at floor



DECAY ROOM

A. Picker Lab Monitor

B. Workspace

C. Lead Lined Safe for Cesium storage

D. L-Block Shield

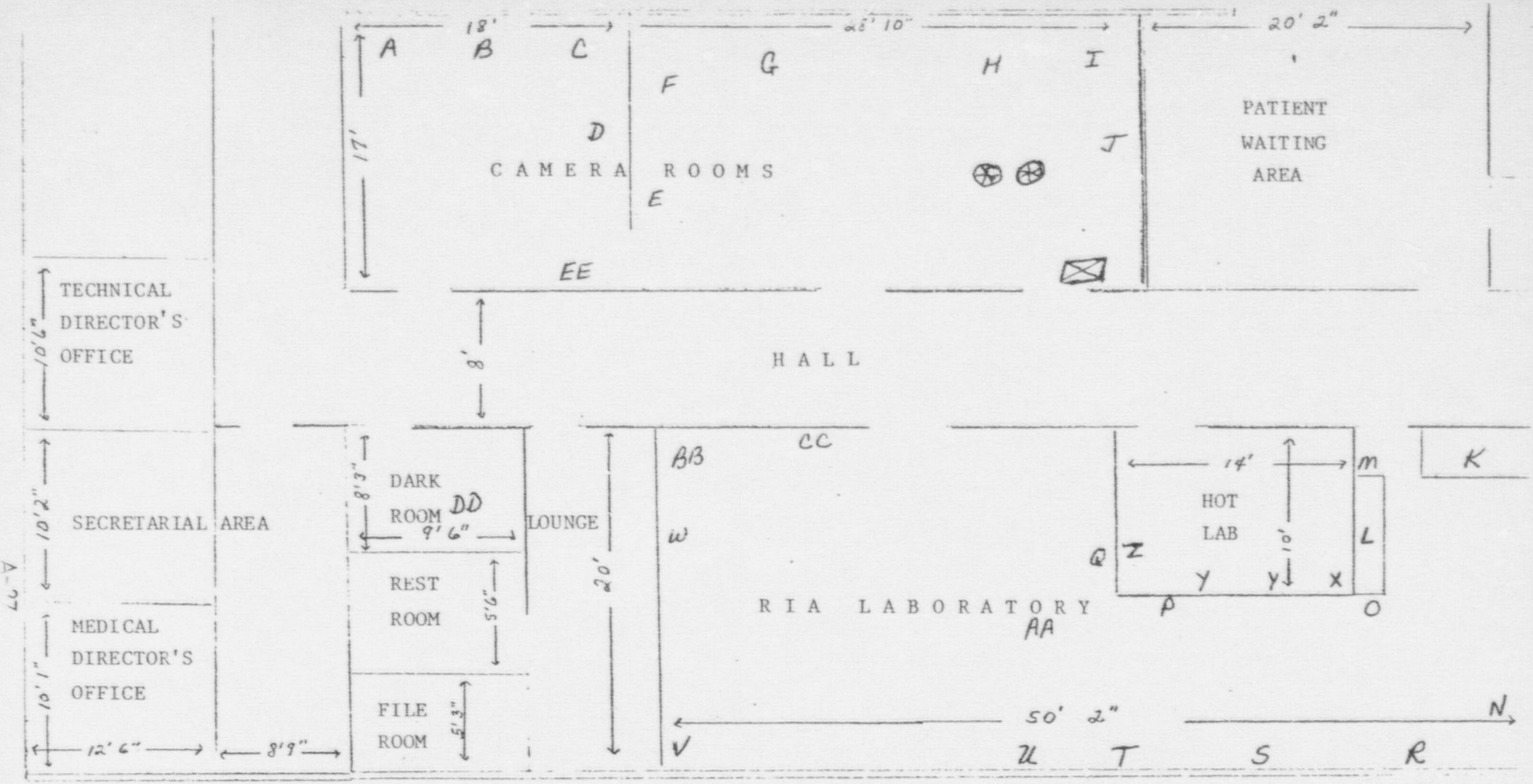
E.,F.,G. Drums for decay storage

H. 100 mCi Cs 137

FACILITIES

AT

Brooks & Elmwood Streets
Charleston, West Virginia
25325



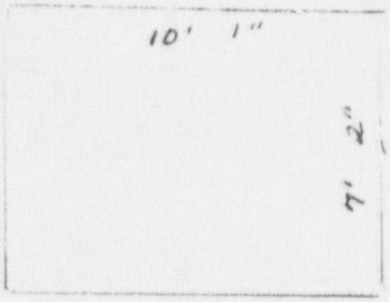
DESCRIPTION OF FACILITIES CAMC-GENERAL DIVISION SOUTH BUILDING SECOND FLOOR NUCLEAR MEDICINE DEPARTMENT

(A) Scaler and Wall Probe
(B) ADAC Computer
(C) Step II
(D) Raytheon Camera
(E) ADAC Computer
(F) Step II
(G) Raytheon Camera
(H) Ohio Nuclear Camera
(I) Ulti[illegible]t
(J) Data System
(K) Fume Hood
(L) BioHazard Hood
(M) Refrigerator
(N) Autoclave
(O) Refrigerator Centrifuge
(P) Freezer & Refrigerator
(Q) Refrigerator Centrifuge
(R) Picker Pace with Programer
(S) Micro-Medic Gamma Counter
(T) NML 5000 Gamma Counter
(U) Centrifuge
(V) Centrifuge
(W) Tri Carb Beta Counter
(X) Picker Autowell
(Y) Stockades (Lead & Glass)
(Z) Dose Calibrator
(AA) H-P Computer
(BB) Ultra Centrifuge
(CC) Spectrophotometer
(DD) Kodak Film Processor
(EE) Xeon trap & Ventilation System
(✱) Air Vent Exhaust Fan
⊠ Air Condition Return

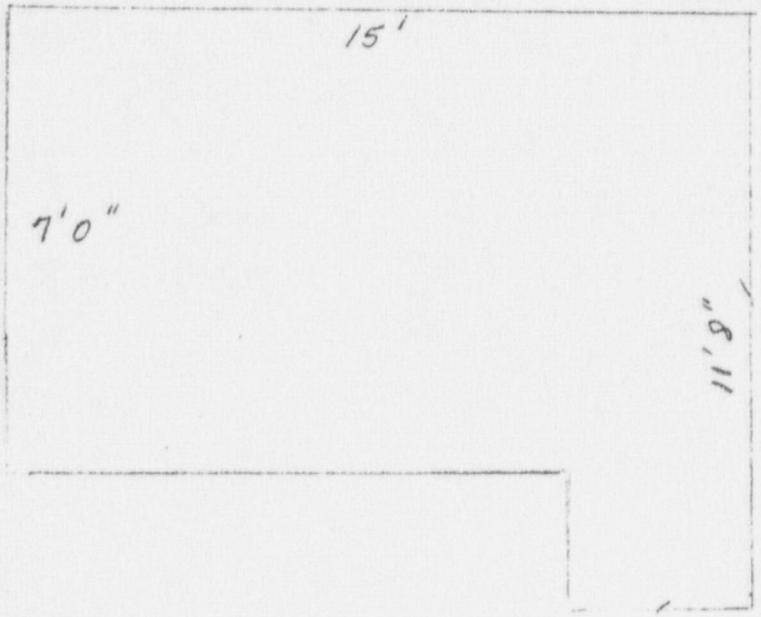
1/8" = 1' 0"

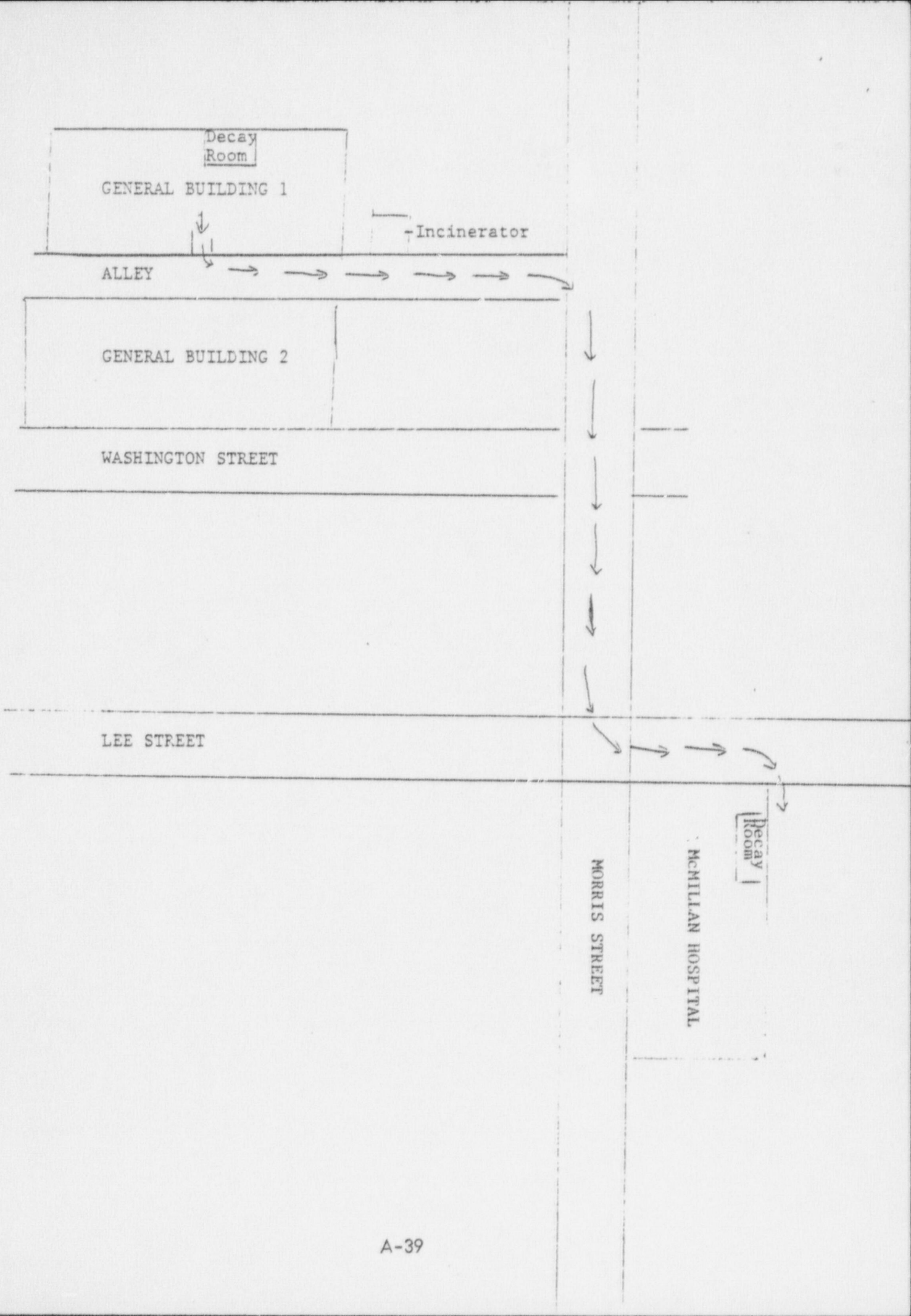
DECAY ROOMS

GENERAL BUILDING 1

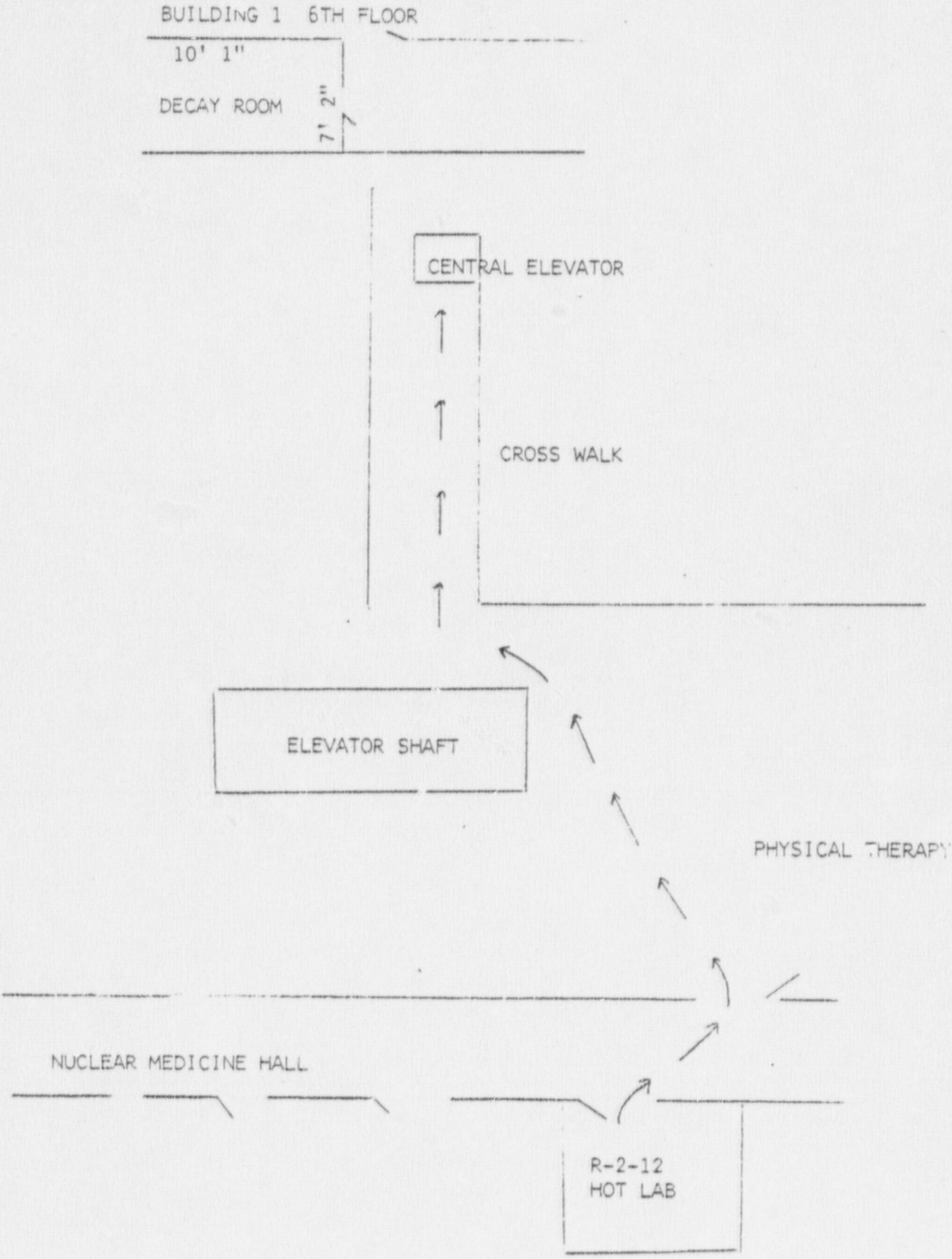


MCMILLAN BUILDING




Decay Room
GENERAL BUILDING 1
Incinerator
ALLEY
GENERAL BUILDING 2
WASHINGTON STREET
LEE STREET
MORRIS STREET
McMILLAN HOSPITAL
Decay Room

ROUTE TO DECAY ROOM



FACILITIES

AT

800 Pennsylvania Avenue
Charleston, West Virginia 25302

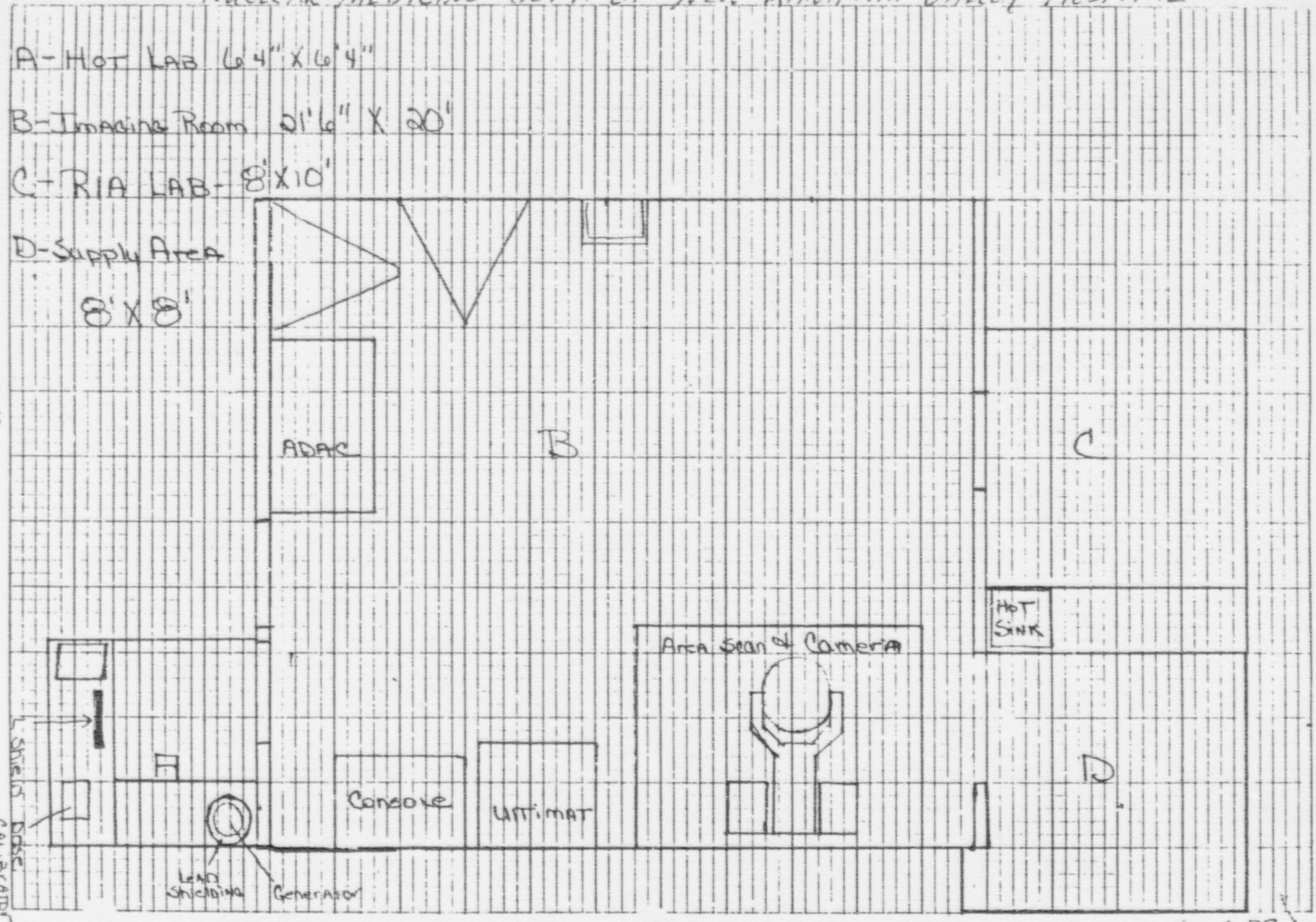
NUCLEAR MEDICINE DEPT. OF NEW KANAWHA VALLEY HOSPITAL

A - HOT LAB 6'4" X 6'4"

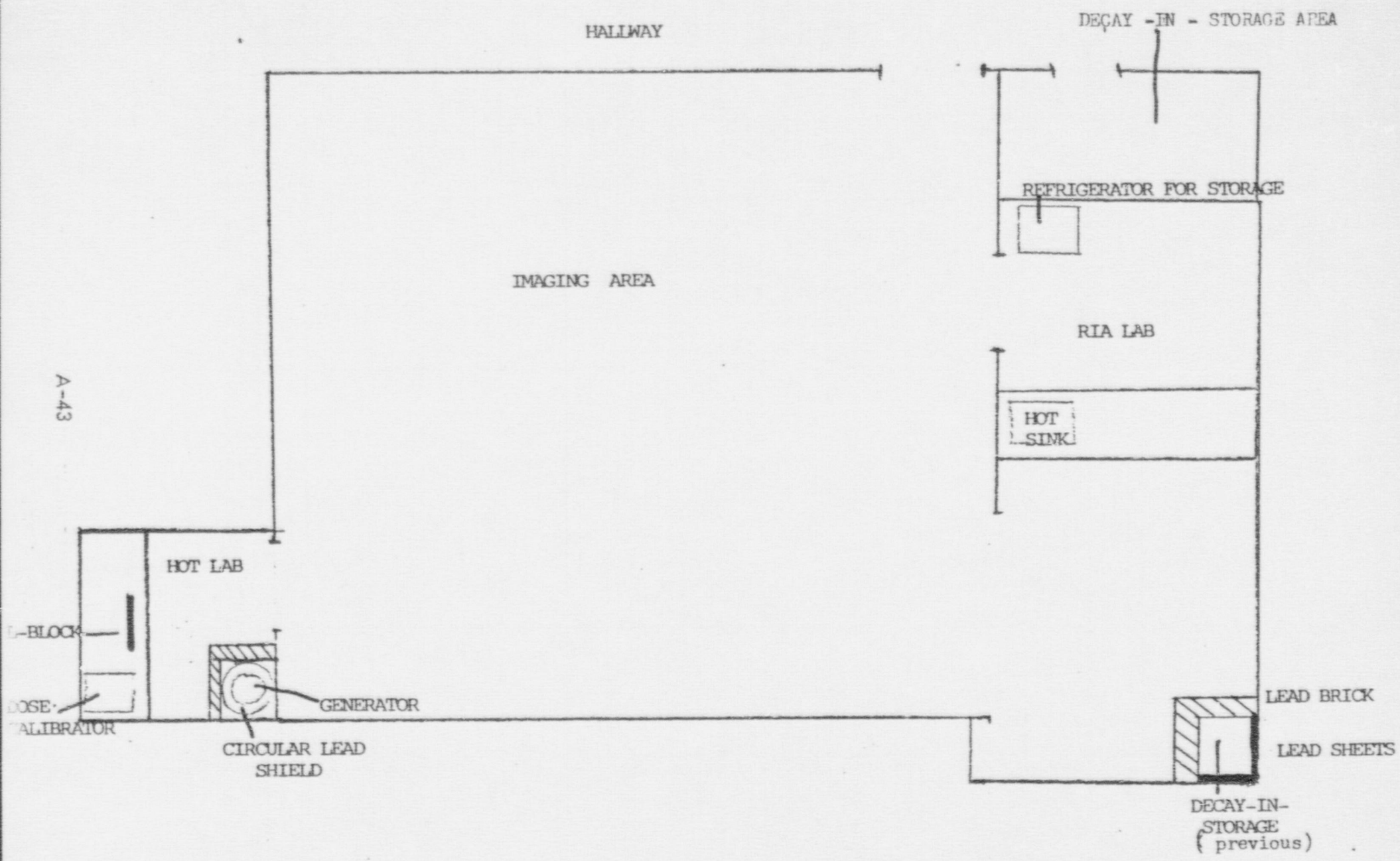
B - Imaging Room 21'6" X 20'

C - RIA LAB - 8' X 10'

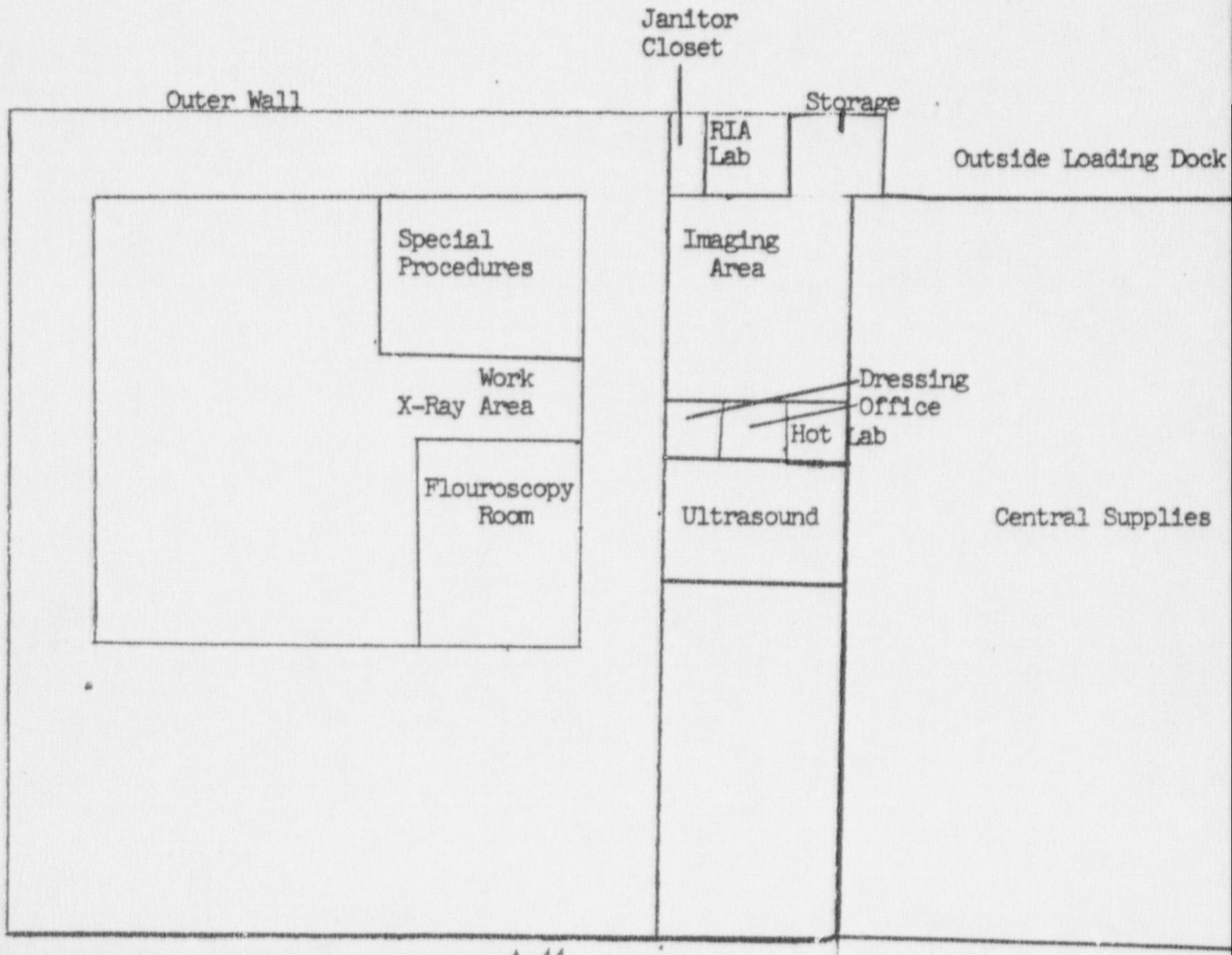
D - Supply Area 8' X 8"



6-1-87


HALLWAY
DECAY -IN - STORAGE AREA
REFRIGERATOR FOR STORAGE
IMAGING AREA
RIA LAB
HOT SINK
HOT LAB
-BLOCK
OSE
ALIBRATOR
GENERATOR
CIRCULAR LEAD SHIELD
LEAD BRICK
LEAD SHEETS
DECAY-IN-STORAGE (previous)

NUCLEAR MEDICINE AND ADJACENT AREAS



PERSONNEL TRAINING PROGRAM

The personnel training program will be given to all personnel who work with or in the vicinity of radioactive materials. The training will be in the form of lectures and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel receive proper instruction in the items specified in 19.12 of 10 CFR Part 19, to include:

A. Areas where radioactive materials are used or stored.
B. Potential hazards associated with radioactive material
C. Radiological safety procedures appropriate to their respective duties.
D. Pertinent NRC regulations.
E. Rules and regulations of the licensee.
F. Pertinent terms of the license.
G. Their obligation to report unsafe conditions.
H. Appropriate response to emergencies or unsafe conditions.
I. Their right to be informed of their radiation exposure and bioassay results.
J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

Personnel will be properly instructed as follows:

1. Before assuming duties with or in the vicinity of radioactive materials.

2. During annual refresher training.

3. Whenever there is a significant change in duties, regulations, or the terms of the license.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Chief Nuclear Medicine Technologist or his designee will place all orders for radioactive material, and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

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

3. During off-duty hours security personnel will accept delivery of radioactive packages in accordance with the procedures outlined in the enclosed memorandum.

4. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:

   a. Ordering of routinely used materials
      (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.
      (2) The written records will be referenced when opening or storing radioactive shipments.

   b. Ordering of specially used materials (e.g., therapeutic uses)
      (1) A written request* will be obtained from the physician who will perform the procedure.
      (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.
      (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

   c. It is essential that written records* be maintained for all ordering and receipt procedures.

* In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

For safely opening packages containing radioactive material, the technologist will:

1. Put on gloves to prevent hand contamination.
2. Visually inspect packages for any sign of damage (wetness, crushed, etc.). If damage is noted, the procedure will be stopped and the radiation safety officer notified.
3. Measure exposure rate at 3 feet from package surface and record. If greater than 10 mR per hour, the procedure will be stopped and the radiation safety officer notified.
4. Measure surface exposure rate and record. If greater than 200 mR per hour, the procedure will be stopped and the radiation safety officer notified.
5. Wipe external surface of shipping container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/100 sq. cm., etc.). Check wipes with a thin end window GM survey meter. The procedure will be stopped if removable contamination is greater than 22,000 dpm/100 sq. cm. above background. The radiation safety officer and health physics consultant shall be notified to determine the "exempt" status of the package with respect to wipe testing. If the package is not exempt, then appropriate notification of regulatory offices will be made.
6. Open the package with the following precautionary steps:
   A. Open the outer package following manufacturer's instructions, if supplied, and remove packing slip.
   B. Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on bottle.
   C. Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
   D. Check also that shipment does not exceed possession limits.
7. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/100 sq. cm., etc.). Check wipes with a well counter/scintillation detector or thin end window GM survey meter, and take precautions against the spread of contamination as necessary. The acceptable level of removable contamination will be 200 dpm/ 100 sq. cm. above background. The procedure will be stopped and the radiation safety officer notified if this level is exceeded.
8. Monitor the packing material and packages for contamination before discarding. If contaminated, treat as radioactive waste. If not contaminated, radiation labels will be obliterated before discarding in regular trash.

Records will be maintained of the results of checking each package (see following sample).

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O.# _____ SURVEY DATE _____ TIME _____

   SURVEYOR _____

2. CONDITION OF PACKAGE:

   _____ O.K. _____ PUNCTURED _____ STAINS _____ WET

   _____ CRUSHED _____ OTHER _____

3. RADIATION UNITS OF LABEL: _____ UNITS (mR/hr)

4. MEASURED RADIATION LEVELS: a Package surface _____ mR/hr

   b 3' from surface _____ mR/hr

5. DO PACKING SLIP AND VIAL CONTENTS AGREE?

   a. Radionuclide _____ yes _____ no difference _____

   b. Amount _____ yes _____ no difference _____

   c. Chem Form _____ yes _____ no difference _____

6. WIPE RESULTS FROM: a. Outer _____ CPM = _____ DPM
   eff=( )

   b. Final source container _____ CPM = _____ DP
   eff=( )

7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mR/hr, CP
   above Bkg.

8. IF PACKAGE WAS SHIPPED WITH DRY ICE, WAS DRY ICE PRESENT IN PACKAGE AT TIME OF RECEIPT? _____ YES _____ NO _____ N/A

9. DISPOSITION OF PACKAGE AFTER INSPECTION: _____

10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, PERSONS NOTIFIED.

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Laboratory coats and other protective clothing will be worn at all times in areas where radioactive materials are used.

2. Disposable gloves will be worn at all times while handling radioactive materials.

3. Hands and clothing will be monitored for contamination at the end of each working day.

4. Syringe shields for preparation of patient doses and administration to patients will be used except in circumstances such as pediatric cases when their use would compromise the patient's well-being.

5. There will be no eating, drinking, smoking, or application of cosmetics in any area where radioactive material is stored or used.

6. Each patient dose will be assayed in the dose calibrator just prior to administration. Any doses that differ from the prescribed dose by more than 10% will not be used.

7. Personnel monitoring devices (film badge or TLD) will be worn at all times while in areas where radioactive materials are used or stored.*

8. TLD finger badges will be worn during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Radioactive waste will be disposed of only in specially designated receptacles.

10. There will be no pipetting by mouth.

11. Generator, kit preparation, and injection areas will be surveyed for contamination daily and will be decontaminated if necessary.

12. Radioactive solutions will be confined in covered containers, plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Radioactive material will always be transported and maintained in shielded containers.

14. The laboratory will be locked when personnel are not present.

15. Emergency notification home telephone numbers will be posted on the door.

16. There will be no storage of food, drink, or personal effects with radioactive material.

17. For therapeutic doses, the following will be verified with the order written by the physician who will perform the procedure:
    A. Patient's name
    B. Radionuclide
    C. Chemical form
    D. Activity

*Personnel monitoring devices will be stored in a designated low background area when not being worn.

18. High activity sources such as bulk radiopharmaceutical vials will be handled behind "L-blocks" and with remote handling devices when practicable.

19. Disposable absorbant pads shall be used to cover work surfaces in radiopharmaceuticai formulation, preparation and dispensing areas.

USE OF MOLY/TECH GENERATORS, PREPARATION OF REAGENT KITS AND DOSE ADMINISTRATION

1. In all cases, all instructions supplied by the manufacturers of the generators and radiopharmaceutical kits will be followed precisely, including procedures for elution, assay, kit preparation, radiation precautions and the use of special equipment such as syringe shields, and other accessories.

2. 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 for contamination daily.

3. Every elution of generators will be assayed for technetium-99m activity and molybdenum-99 breakthrough contamination. The eluates will not be used if there is more than one (1) microcurie of Moly-99 per millicurie of technetium-99m or more than five (5) microcuries of Moly-99 per administered dose of technetium-99m.

4. The activity of all radionuclides or radiopharmaceutical doses to be administered to patients will first be determined by mathematical calculation. Once drawn, the total activity contained in the syringe will be double checked by use of the dose calibrator. Except for this determination, the syringe will be kept in the syringe shield and/or pig. All radiopharmaceuticals will be assayed just prior to administration to the patient.

5. Patient dose information of administered technetium-99 and all other administered radioactive materials will be recorded in the patient dose log.

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 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: _____*
OFFICE PHONE: _____
HOME PHONE: _____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

_____
_____
_____

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

AREA SURVEY PROCEDURES

The following area survey procedures will be conducted by the Chief Technologist of the department or his deisgnee, in each area where radioactive material is used or stored:

1. Preparation and injection areas will be surveyed on a daily basis with an appropriately low range G-M survey meter and decontaminated if necessary.

2. All other laboratory areas will be surveyed daily via a measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem per hour.

3. A weekly survey will consist of a series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 sq. cm. for the contamination involved.

4. A permanent record will be kept of all survey results, including negative results. The record will include:

   A. Location, date, and type of equipment used.

   B. Name of person conducting the survey.

   C. A drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   D. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   E. Detected contamination levels, keyed to locations on drawing.

   F. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

5. The area will be cleaned if the contamination level exceeds 200 dpm per 100 sq. cm.

NOTE: For daily surveys where no abnormal exposures are found, only the date, indentification of the person performing the survey and the survey results will be recorded.

WASTE DISPOSAL

In accordance with Section 20.303 of 10 CFR 20, allowed quantities in authorized concentrations of certain generated liquid radioactive waste (such as radioimmunoassay wastes) are disposed of via the sanitary sewage system.

Other radioactive wastes are segregated into one of three groups based on half-life.

A. Short half-life waste (radionuclides with the half-life of ^{99m}Tc or shorter) is collected into an appropriately labeled container in the formulation area of the Nuclear Pharmacy. This waste is then placed in an appropriately identified cardboard container and placed to decay in the storage area. The container will be minimally labeled with "Short half-life waste" and the date placed to decay. This waste is retained in storage until it decays to background levels, is recorded as disposed on the correct waste disposal form, and is then discarded to incineration. Placement to decay occurs at least weekly but as required.

B. Intermediate half-life waste (radionuclides with half-lives greater than ^{99m}Tc but less than 14 days like Ga-67, I-123, I-131, Xe-133, Tl-201) are collected into an appropriately labeled container in the formulation area of the Nuclear Pharmacy. This waste is then placed in an appropriately identified cardboard container or steel drum and placed to decay in the storage area. This is done weekly. The container will be minimally labeled with the words "Intermediate half-life" and the date placed to decay. It is retained in the waste storage area until it decays to background levels, is recorded on the intermedicate waste disposal sheet, and is then discarded to incineration.

C. Long half-life waste from radionuclides with half-lives greater than 14 days is collected in the same manner as described above and placed in an appropriately identified cardboard container and then into a steel drum in the storage area. This is done as required due to the infrequent usage of these isotopes. The container will be minimally labeled "Long half-life" and the date placed to storage. The volume of this waste is very limited and final disposal will ultimately be effected by an approved commercial firm when required.

^{99}Mo to ^{99m}Tc generator columns are kept separate from other wastes so that they may be monitored separately to ensure decay to background levels prior to disposal.

Adequate lead or other suitable shielding will be provided as necessary to insure that radiation exposure levels are held to the lowest reasonable level while the waste is in storage. The waste storage areas are locked when staff personnel are not present. This area is surveyed at least weekly.

I-125 and Co-57 waste from the RIA laboratory may be compacted. To decrease volume, the two radionuclides are separated prior to compaction. Compaction of liquid I-125 waste does not pose a volitility problem since the majority of the I-125 has been disposed of under the provisions of 10 CFR 20.303. The trash compactor is labeled in accordance with 10 CFR 20.203.

Tc-5 WASTE DISPOSAL

DISPOSAL DATE	INITIAL BOX DATE	BACKGROUND READING	CONTAINER READING	RADIATION SAFETY OFFICER(APPOINTEE)

INTERMEDIATE HALF-LIFE WASTE

DISPOSAL DATE	INITIAL BOX DATE	BACKGROUND READING	CONTAINER READING	RADIATION SAFETY OFFICER(APPOINTEE)

LONG HALF-LIFE WASTE

DISPOSAL DATE	INITIAL BOX DATE	BACKGROUND READING	CONTAINER READING	RADIATION SAFETY OFFICER(APPOINTEE)

All 99m Tc Products

99m Tc-0.25 days

II.

Intermediate Half Life

> 99m Tc < 14 days

67 Ga----------3.24 days

99 Mo----------2.8 days

123 I----------0.55 days

131 I----------8.05 days

133 Xe----------5.27 days

201 Tl---------- 3.08 days

III.

Long Half Life > 14 days

32 P----------14.3 days

51 Cr----------27.9 days

57 Co----------270 days

58 Co---------- 71.3 days

60 Co---------- 5.3 years

75 Se----------120.4 days

125 I---------- 60.2 days

169 Yb---------- 31.8 days

CHARLESTON AREA MEDICAL CENTER

3200 MacCorkle Avenue, S. E. • Charleston, West Virginia 25304 • P.O. Box 4396
304/348 5432

SYRINGES AND NEEDLES:

All needles and syringes will be segregated into one of three classifications, like the solid waste. They are:

1. Tc-99m Syringes and needles.

2. Intermediate half life isotope syringes and needles

3. Long half life isotope syringes and needles.

1. Tc-99m syringes will be placed in the large Tc-99m waste receptical after having the needle clipped off. The syringes will be discarded with the regular Tc-99m trash every week. The needles will be held until the box is filled. It will then be taken to the decay area and stored for 12 half lives before they are disposed in the special trash. All waste disposal records are to be logged appropriately.

2. Intermediate and Long half life isotopes. Seperate needle cutting boxes and syringe containers for this waste has been made. When these boxes become full they will be dated and taken to the decay area. The intermediate half life isotope syringes may be either stored until they read background/or if appropriate, put in the large steel drum with other solid waste.

The long half life isotope syringes will be stored in its seperated container and discarded when a disposal vendor picks up other long lived solid waste.

RADIONUCLIDE THERAPY PROCEDURES

When handling is necessary, radionuclide therapy doses will remain in the shipping shield whenever possible. If the dose must be removed from its shield, remote handling equipment will be used whenever possible. Additionally, the dose will be handled in a well ventilated area utilzing available radiation safety equipment ("L-blocks", etc.). When handling, the dose will be positioned between the worker and the ventilation exhaust port such as directly under the exhaust hood in the Nuclear Pharmacy. Personnel handling the dose will be properly attired/prepared (wearing disposable gloves, lab coats, etc.).

Radionuclide therapy doses will be ordered such that the activity is as close as possible to that ordered by the tending physician. The dose vial will not be opened unless absolutely necessary such as in the case of assay or administration. Only contemporarily available therapy doses incorporating stabilizers or physical forms which limit volatility will be used.

RADIONUCLIDE THERAPY PROCEDURES

Patients who receive therapeutic doses of unsealed radionuclides (nearly always I-131) who require admission will be admitted into a private room with private bathroom facilities. Absorbant coverings will be spread over the floor area surrounding and immediately adjacent to the patient's bed such that the area surrounding the patient's bed which is covered approximates two feet in width with additional coverings under the collection container in the event of a urinary catheter. Additionally, the bathroom floor will be completely covered along with a walkway connecting these two areas. All these coverings will be securely affixed to the floor.

Other flat surfaces shall also be similarly covered. These include bedside tables, overbed tables, and other areas frequently used by the patient. Two waterproof recepticles will be provided in the patient's room. One will be labeled "Disposables" and the other "Linen".

In so far as possible, all items used by the patient including but not limited to plates, cups, eating utensils, pitchers, trays, and other such items are to be disposable. After use, these items are to be placed into the provided waste recepticle.

Small, non-disposable items such as the nurse call control or telephone need not be covered with plastic so that patient use is not incumbered. However, such items are to be carefully monitored upon patient discharge and if contaminated be removed from the room by Nuclear Medicine personnel for decontamination or storage for decay. These items will be replaced by non-contaminated ones.

The inside and outside door knobs on the patient's bathroom door will be covered with waterproof plastic. Nondisposable patient care items which may be required such as thermometers or sphygmomanometers are not to leave the patient's room after being used in the patient's room unless surveyed and found not to be contaminated by Nuclear Medicine personnel.

Bed linen, towels, washcloths and other fabric items are not to be removed from the patient's room when no longer needed, but are to be placed into the provided recepticle.

To insure constant awareness, a "Caution - Radioactive Materials" sign will be posted midway between the center and non-hinged side of the routinely half-way closed door of the patient's room and on the wall near the head of the patient's bed. The patient will be dosed with the therapeutic activity of the radionuclide ordered by the attending physician. The empty therapy dose container will be returned to its complete shield and returned to the Nuclear Medicine Department so that it will not contribute to any measured exposure value in the patient's room. As soon as the dose is administered and its container is not contributing to the exposure rate in the room, the initial survey of the patient's room will be conducted. Exposure rates will be determined at the patient's bedside closest to the organ with the greatest concentration of the dose, at one meter from the approximate center of the organ with the greatest concentration of the dose, at 10 feet from the bed, and at the entrance to the room.

Such surveys will be conducted twice daily, morning and afternoon, during the patient's admission. The measured exposure rates will be used to determine how long a person may remain at these positions and this data will be recorded in the patient's chart and on the door to the room. A "Radionuclide Therapy Data Form" on which this data is recorded will be placed in the patient's chart and on the door to the patient's room beside the "Caution" sign toward the center of the door.

During each survey, the recepticles for contaminated items (linen and disposables) will be checked. As indicated, they will be removed from the patient's room for survey and disposition depending on the contamination level, if any, found. Removed recepticles will be replaced by fresh ones.

The patient's urine will not be collected. The patient may make normal use of the bathroom facilities.

A copy of the "Instructions to Visitors" and the "Instructions to Patients" are to be presented to the patient and explained. Any patient questions will be answered. Also, a copy of the "Instructions to Visitors" will be posted on the door to the patient's room beside the "Caution" sign to the side next to the non-hinged side of the door.

Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated, if necessary, and all radioactive waste and waste containers will be removed. Postings will be removed from the patient's door.

Special attention is to be given to any drainings from the patient's body, bandages, or wet areas on linen. These are to be surveyed and if contaminated, appropriate disposition will immediately ensue.

The patient will be discharged when measured exposure rates document that the activity remaining in the patient's body is less than 30 mCi. in the case of I-131.

INSTRUCTIONS TO NURSES

1. Wear disposable gloves when providing nursing care to the patient or handling items the patient has used or contacted.

2. When patient care is completed, dispose of the plastic gloves in the provided recepticle labeled "Disposables" and wash hands using facilities other than those used by the therapy patient. Touch nothing during the time between glove removal and hand washing.

3. In so far as possible, all items used by the patient including but not limited to plates, cups, eating utensils, pitchers, trays, and other such items are to be disposable. After use, these items are to be placed into the provided recepticle labeled "Disposables".

4. Access to the therapy patient's room is to be prohibited except as necessary to provide patient care.

5. Except when patient privacy is required or needed, the door to the patient's room should not be constantly closed. This will not only maintain an atmosphere suitable to treatment (not one of imprisonment) but will also facilitate nursing staff observation of occurrances which may lead to contamination (like vomiting) and facilitate the conversations necessary to nursing care between the nursing staff and the patient at a practicable distance.

6. Nurses are to spend only that amount of time necessary to perform required health care tasks near the patient.

7. Visitors are prohibited during the first 24 hours after dose administration.

8. Visitors must be 18 years of age or older.

9. In the absence of specific needs, visitors should not be permitted during the course of the admission.

10. Should a therapy patient need to leave his/her room for medical reasons, contact the Nuclear Medicine Department for instructions and assistance. Otherwise, the patient is to remain in the room.

11. Nurses, visitors, or other persons who are pregnant should not enter a therapy patient's room or provide care to the patient.

12. Any dressings should be changed under physician direction, while wearing disposable gloves, and with Nuclear Medicine personnel present. Said dressings are to be handled as contaminated items.

13. If a patient is bedridden, a urinal and/or a bedpan designated for the exclusive use of the therapy patient is to be provided. The urinal or bedpan is to be flushed several times with hot, soapy water after each use.

14. If a nurse helps to collect patient excreta, disposable gloves are to be worn. After flushing the collecting container, hands are to be washed with the gloves on using the patient's facilities, the gloves removed and discarded in the recepticle for disposables, and the hands washed again using facilities other than those used by the patient. The nurse is to touch nothing during the time between removal of the gloves and the following hand washing.

15. Vomiting within 24 hours of oral administration or urinary incontinence or excessive sweating within 48 hours of administration may result in radioactive contamination of linen, garmets, the floor, or other areas. In any situation where contamination may exist or a "spill" or release of radioactive materials may occur as in the case of incontinence, call the Nuclear Medicine Department immediately. If required, handle any contaminated items or substances containing radioactive materials only while wearing plastic gloves and very carefully so as not to spread contamination.

16. In the event any individual is aware of or suspects that any part of a person (shoes, clothing, skin, etc.) is contaminated, notify the Nuclear Medicine Department or the Radiation Safety Officer immediately. The person in question shall remain in an area adjacent to the patient's room (in the hallway by the patient's door, for example) and is not to walk about the hospital. If hands become contaminated, wash them immediately with soap and water.

17. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

18. When the patient is discharged, call the Radiation Safety Officer or the Nuclear Medicine Department and advise that the room needs to be surveyed for contamination before remaking the room. Touch nothing in the room until the final survey is completed and the room cleared for use by the Nuclear Medicine Department after the final survey.

19. When contaminated wastes are transported to the waste storage area, precautions will be taken to minimize external radiation to personnel. Stored wastes will be appropriately stored to maintain exposures to personnel in restricted and unrestricted areas ALARA.

20. In the event of questions, concerns, or unusual circumstances, contact the Nuclear Medicine Department.

21. Other than the patient, smoking is not permitted in the room.

INSTRUCTIONS TO PATIENTS

1. Movements are to be confined to the absorbant coverings on the floor during the first 24 hours of admission and as much as possible thereafter.

2. When moving about the room, the patient should wear plastic gloves during the first 24 hours of admission.

3. After wearing, plastic gloves shall be discarded in the recepticle labeled "Disposables".

4. Patients are not to leave the room.

5. Patients should remain in bed as much as possible during the first 24 hours after the dose is administered.

6. Patients must remain in bed while visitors are in the room.

7. In the absence of specific needs, visitors should not be permitted during the entire course of the admission.

8. Flush the toilet at least 3 times after each use.

9. Other than the patient, smoking is not permitted in the room.

INSTRUCTIONS TO VISITORS

1. Personal items such as the patient's restroom, telephone, bed position control, etc. are not to be used by visitors.

2. Visitors are to make their presence known at the nurse's station.

3. Visitors are to avoid contact with the patient and the absorbant coverings on the floor and flat surfaces.

4. Visitors are to remain at least three feet from the patient.

5. Visitors are prohibited during the first 24 hours after administration of the dose.

6. Visitors should not be permitted during the course of the admission.

7. Visitors must be 18 years of age or older.

8. Visitors who are pregnant are prohibited.

9. Other than the patient, smoking is not permitted in the room.

RADIONUCLIDE THERAPY DATA FORM

Patient Name: _____ Date Admitted: _____

Physician: _____ Room No.: _____

Administration Data - Radionuclide: _____ Date & Time: _____

Activity: _____ Route: _____

Survey		Exposure Rate in mR/hr				Recommended Length of Stay in min.			
Date	Time	Bedside	1 meter	10 feet	Room Door	Bedside	1 meter	10 feet	Room Door

Date Discharged: _____

As a result of organizational changes at the Charleston Area Medical Center, the rooms to be used for the performance of brachytherapy must be changed from 574 and 589 to rooms 474 and 489. With the exception of the patient rooms overhead, specifically these same rooms of 574 and 589, these fourth floor rooms are identical to those previously used, overhead rooms to which amendment 19 of this license, license #47-15473-01, was applicable.

Due to the identity of the involved rooms, the same statements and illustrations forwarded in September, 1986 which resulted in Amendment 19 continue to apply with only minor revision. As the provisions and conditions of Amendment 19 continue to be desired as part of license #47-15473-01, these illustrations and revised statements are included herein as pages A-69 thru A-72.

Patients on whom Cleveland Radiation Therapy Consultants perform brachytherapy are admitted to CAMC, Memorial Division during the procedure. The procedure is performed using sealed Cesium-137 sources the ownership, possession, use, storage, and transport of which are the responsibility of Cleveland Radiation Therapy Consultants and subject to their U.S.N.R.C. license which is license #47-15717-03. These sources had been the responsibility of CAMC but were transfered as per documents previously forwarded to you and of which copies are attached as pages A-73 thru A-78 for your convenience.

Sources are transported from their place of storage to the patient's room or operating room in a commercially designed lead carrier (Radium Chemical Company). Immediately after source placement/insertion, exposure rates measured and documented as per the attached pages A-79 and A-80.

Based on the exposure rates determined, nursing staff are advised via forms on the door to the patient's room and in the patient's chart (page A-79) of the daily length of time they may spend in these proximities to the patient. At the conclusion of the therapy and before the patient is discharged, the removed sources are counted and a survey of the patient's room is effected.

The patient is seen twice daily by the radiotherapist with visual inspection to ensure that the device is in proper position and sources are in place. At the time of discharge sources are removed from the patient and placed in a portable carrier with visual verification of proper number of sources removed. This is simple and reliable with the Fletcher-Suit afterloading system. Repeat verification of sources removed takes place shortly thereafter when the sources are replaced in their storage location. A sample inventory form is attached as page A-81.

Radiation safety procedures followed for therapeutic use of sealed sources are attached as pages A-82 thru A-84.

Two hospital rooms were selected in which all brachytherapy patients will be admitted for treatment. These are rooms 474 and 489. They were selected because

1. they are corner rooms;

2. they possess 2 sides which very infrequently accomodate persons especially for more than a few minutes;

3. three other sides (hallway, room above, and room below) from the patient (source) which result in compliant exposure levels;

4. this leaves minimal unrestricted area (a single adjacent room) demanding close exposure level scrutiny; and

5. they are private rooms with bathrooms.

These rooms, 474 and 489, are mirror images of each other. There are illustrations of them attached, and on these illustrations are liberally estimated 3 mR/hr. lines as produced by the nominal load of 150mCi of 137Cs (60mgm Ra equivalent). Please note the following criteria pertinent to the illustrated theoretical exposure level.

This 3mR/hr. line:

1. is the maximum possible exposure rate estimate,

2. considers no attenuation by the patient,

3. considers no air attenuation,

4. considers a conservative wall attenuation coefficinet, and

5. is at waist height. The mR/hr. line radius shortens as distance above and below waist height increased due to spheroid geometrial relationship to isocenter (source in patient), and

6. is greater than actual measurements the values of which are related in the subject Notice of violation.

In addition, statistics were reviewed so that the liklihood of personnel exposure could be assessed relative to the illustrated exposure level.

Since August of 1981, this facility has averaged just under 24 brachytherapy cases per 12 month period. These cases represent a total average 75 hours each in the room containing the therapy patient. From the standpoint of hospital employees, this average number of hours closely approximating three 24-hour periods indicates the opportunity of an employee to be in the vicinity of such a procedure three 8-hour shifts. Consider the restricted area in the adjacent patient room on the attached illustration. Assuming an average exposure rate of 3mR/hr. (and this is felt to be a substantial over-estimation) received in the vicinity of this areas, an employee would have to spend 166 hours there to receive a total of 500mR.

Certainly it is unlikely that any employee would spend 166 hours out of a possible 576 (a yearly average of 24 patients times 24 hours (three 8-hour shifts) per patient) with any series of patients in this adjoining room and obviously such a length of time would not be spent in the small affected area of this room.

For a variety of obvious reasons like

1. these brachytherapy data are derived from 12 month time increments,

2. current medico-economics mandating short patient stays, and

3. trends toward cutpatient care

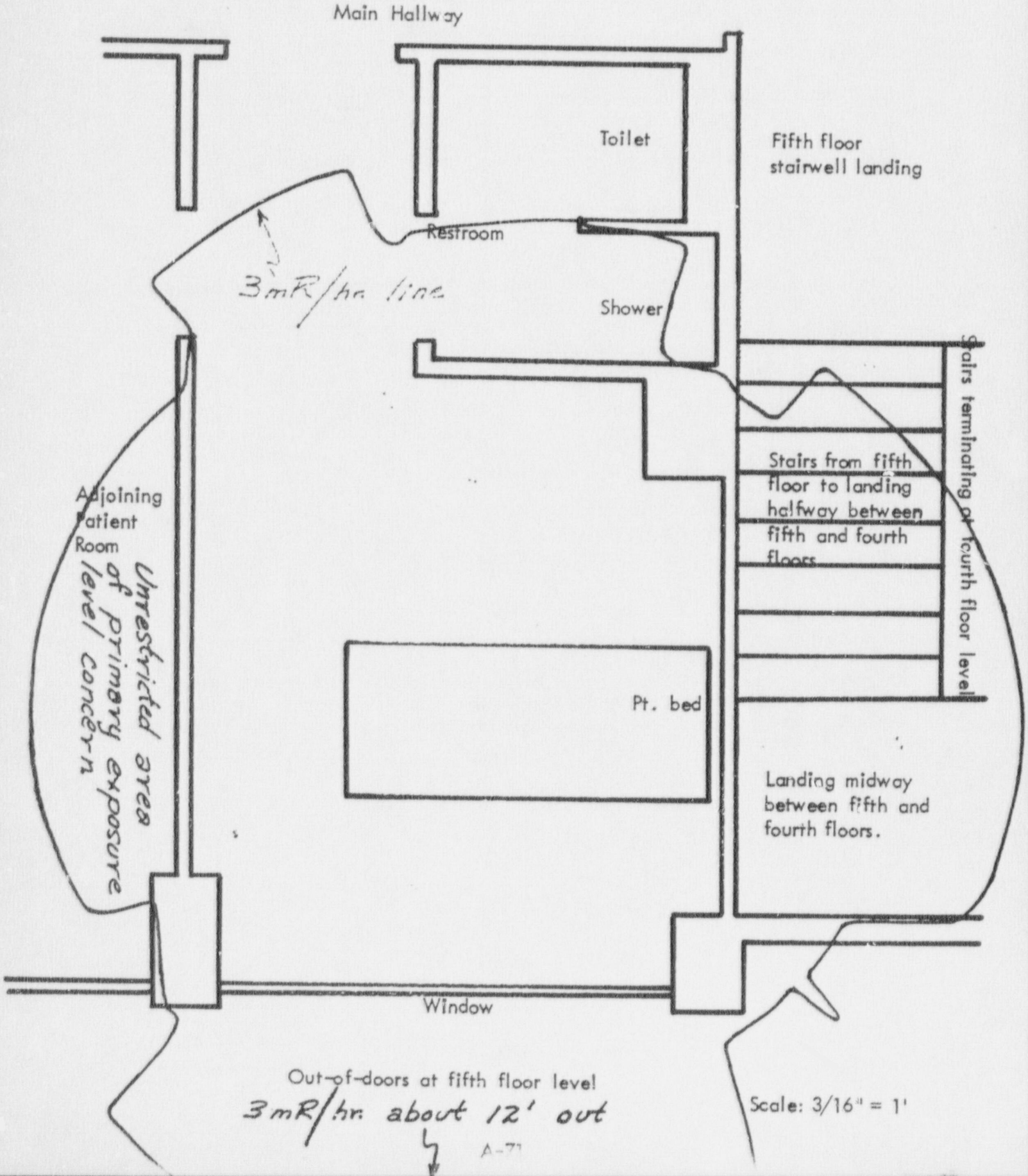
It seems even less likely that any visitor to the hospital or other general population non-occupational individual would ever be afforded the opportunity to be in the room for 166 hours and certainly not to be in it that long while therapy was underway next door, and definitely not in the small confined, involved area for 166 hours.

Obviously it is unlikely that a patient occupying this adjoining room whose bed is at the wall opposite the wall separating the adjacent brachytherapy room, could spend the necessary 166 hours in the small area approximating the theoretical 3mR/hr exposure rate.

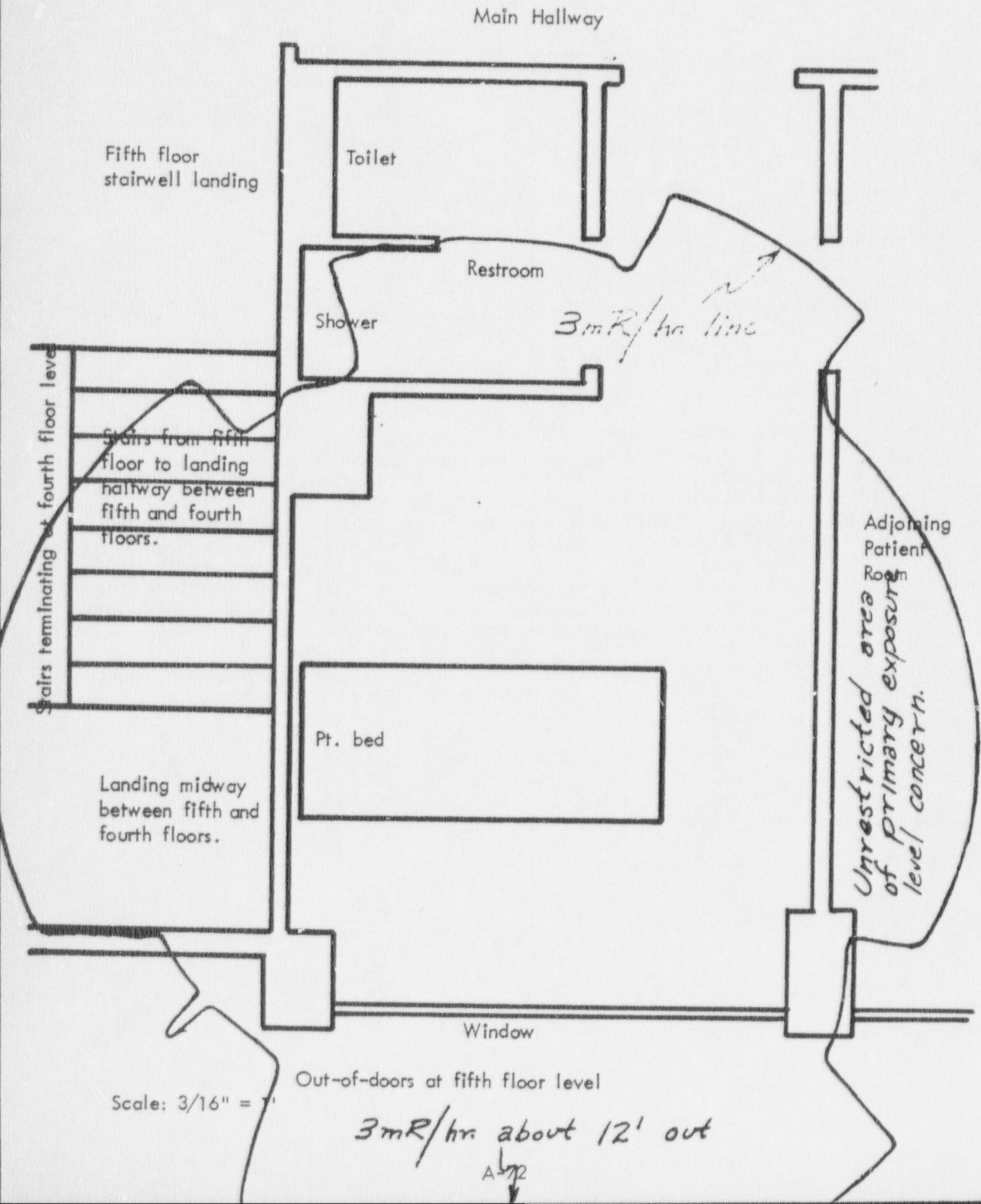
It seems even less likely that anyone could spend such a sufficient length of time on the stairway or on the landing (the landing half-way between the brachytherapy room floor and the floor below) so as to receive any significant exposure.

Since it has been demonstrated that these limits are certainly not likely to cause any individual to receive a dose to the whole body in excess of 500 mREM per year, it is request in accordance with 10 CFR 20.105 (a) that as a result of brachytherapy procedures exposure rates of 3mR/hr or less be authorized in adjoining unrestricted areas but only 3 feet or less into them.

PATIENT ROOM 474



PATIENT ROOM 489



RADIATION
THERAPY
CONSULTANTS, P.C.

A. Don Wolff, M.D.

10 June 1985

Nuclear Regulatory Commission
Suite 2900
101 Marietta Street
Atlanta, Georgia 30323

Attention: Chief of Materials Section

Dear License Reviewer:

Please find attached an application for a materials license. This is somewhat of a special case in that we currently own a supply of encapsulated Cs 137 sources for therapeutic intracavitary use. These sources are physically located at the Memorial Division of the Charleston Area Medical Center and are covered under their license. In the interest of relieving an over crowded area in the hospital, relieving the hospital of the responsibility for the sources and for placing the sources under our direct control, we are planning on relocating the sources within the physical confines of our department. Our department is physically connected to the hospital via a tunnel, and relocation of the sources would not involve use of any public highways, roads or motorized vehicles.

The move will be under the direct supervision of Warren Bryant, Radiation Safety Officer for Cleveland Radiation Therapy Consultants. (See the attached page (s) for relocation procedures)

The radiotherapists listed as users will continue to utilize the facilities of Memorial Division, CAMC for patient care during brachytherapy procedures. The radiation safety procedures currently outlined under the hospitals (CAMC) license will adhered to, as they have in the past.

Sincerely,

A. Don Wolff, MD
Director
Cleveland Radiation Therapy Consultants
ADW/sll

James Crews
President
Charleston Area Medical Center

Suite B-1, 3100 MacCorkle Avenue, SE
Charleston, West Virginia 25304
(304) 345-0666

RELOCATION PROCEDURES FOR Cs 137 SOURCES

Current owners - Cleveland Radiation Therapy Consultants

Current location - Memorial Division, CAMC 1st floor.

Projected location - Sub-basement of Medical Staff Office Building, Suite B 1

1. After receiving medical license from NRC, I will, via a written notice, relieve Memorial Division, CAMC of responsibility for said sources after physical inventory indicates that all sources are accounted for - this notification will be via the hospital radiation safety officer.

2. I will take immediate physical possession of said sources and transfer them to a new location as indicated in the 313M license application. The sources will remain in a locked safe during transport and will be accompanied by myself at all times.

3. Upon arrival in the new location, the sources will be reinventoried. Safe guards for storage of radioactive material will be effected at this time in accordance with NRC regulations and/or terms of the medical license.

4. The hospital radiation safety officer will be made aware of the completion of transfer in order to effect appropriate hospital license amendments and to inform the NRC of completion of said transfer.

Warren Bryant

Warren Bryant, Radiation Safety Officer
Cleveland Radiation Therapy Consultants
WB/sll

RADIATION
THERAPY
CONSULTANTS, P.C.

A. Don Wolff, M.D.

Warren Bryant
Radiation Safety Officer
Cleveland Radiation Therapy Cons.
Charleston, WV 25304

Ken Dwyer, M.D., R.S.O.
CAMC Memorial Division
Charleston, WV

Dr. Dwyer;

This is to inform you that on 10 January 1986 @ around 1330, I will take physical possession of and assume all resposibility for the following radioactive active sources:

1.	Color Code	Model Number	Serial Number	Nominal mg. Ra. eq.	Nominal mCi, Cs-137
	Green	6D6C-CC	0204 0215 0232 0236	10	25
	Yellow	6D6C-CC	0185 0189 0193 0194 0202 0207	15	37.5
	Orange	6D6C-CC	0181 0182 0186 0193	20	50

2. The J.L. Shepherd Model 10 calibrator c the 100mCi (nominal) Cs^{137} source.

Suite B-1, 3100 MacCorkle Avenue, SE
Charleston, West Virginia 25304
(304) 345-0666

RADIATION
THERAPY
CONSULTANTS, P.C.

A. Don Wolff, M.D.

In addition to the above, I will be removing the lead safe, L-block and supporting table. (This has been pre-arranged with Ridge Connant)

Before taking possession, I will ascertain that all sources are accounted for and will then lock the safe containing the sources prior to movement. I will need from you the most recent wipe test report and any paperwork pertaining to the sources.

If you need specific information concerning the move and/or would like to be present during the same, contact me, otherwise I will notify you upon completion of the project.

Find attached the agreement between Dr. Wolff & Mr. Crews, the approved relocation procedures and our NRC medical license.

Sincerely,

Warren Bryant 31Dec85

Warren Bryant

cc: Ridge Connant

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Charleston, West Virginia 25304
(304) 345-0666

CHARLESTON AREA MEDICAL CENTER

3200 MacCorkle Avenue, S. E. • Charleston, West Virginia 25304 • P.O. Box 4396
304/348-5432

January 7, 1986

Mr. Warren Bryant
Radiation Safety Officer
Cleveland Radiation Therapy Consultants
Suite B-1
3100 MacCorkle Avenue, S.E.
Charleston, WV 25304

Dear Mr. Bryant

This is to formalize the clarification of confusion the awareness of which was induced by your letter of December 31, 1985 addressed to Dr. Ken Dwyer. Below comments relate current understandings based on our telephone conversation yesterday.

The supportive/authorizing documents needed by this office as per previous discussions have been acquired from Dr. Dwyer. A review of these documents reveals no apparent problems, the 100mCi Shepherd Model 10 calibrator is not to be included in the radioactive sources being transferred, and the Assistant Radiation Safety Officer of the Charleston Area Medical Center will be present during the relocation of the therapy sources.

Also, a report of a less-than-six-month old wipe test is provided via attachment hereto. These sources were also wipe tested in mid-December but the report has not yet been received. Upon receipt a copy will be forwarded to you.

Sincerely

Ridgely G. Conant, Director
Nuclear Medicine Department

dlw

Attachment

cc: Robert Savage
James Wente
Kenneth L. Dwyer, M.D.
file