



Veterans
Administration

FEB 11 1985

'85 FEB 22 NO:19



ADCMD for Operations (115)
Veterans Administration Central Office
Washington, DC 20420

SUBJ: Renewal of NRC Byproduct Material License # 19-07187-01

1. Application for renewal of NRC Byproduct Material License # 19-07187-01 is enclosed in duplicate.
2. It is requested that all statements and representations made in the past be deleted and that the license be renewed based only on statements made in the enclosed application.
3. Your cooperation is appreciated.

Robert Dawson
FOR AND IN THE ABSENCE OF
ROBERT DAWSON
Director

Enclosure

RECEIVED

FEB 19 1985

NUCLEAR MEDICINE SERVICE
(115)

*Reviewing and administrative
representations on the
Education Safety Committee are
not needed.*

FEE EXEMPT

8509120415 850816
REG1 LIC30
19-07187-01 PDR

In Reply Refer To: 641/115

James J. Smith M.D.
FEB 19 1985
JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

OFFICIAL RECORD COPY

ML10

18703

APPLICATION FOR MATERIALS LICENSE — MEDICAL

Approved:
GAO R0557

INSTRUCTIONS — Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.

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

Veterans Administration Medical Center
Nuclear Medicine Service
Perry Point, Maryland 21902

TELEPHONE NO.: AREA CODE 301 : 642-2411 x532

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

Same as 1a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Radhakrishna V.C. Kamath, M.D.

TELEPHONE NO.: AREA CODE 301 : 642-2411 x532

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

a. ☐ NEW LICENSE

b. ☐ AMENDMENT TO LICENSE NO. _____

c. ☒ RENEWAL OF LICENSE NO. 19-07187-01

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

Radhakrishna V.C. Kamath, M.D.
Henry N. Wagner, 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.)

Radhakrishna V.C. Kamath, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	3.0	IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	50
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000 each	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP VI					

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

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
57-Co	gel in plastic vial	5.3 mCi	Calibration of the Dose calibrator

"OFFICIAL RECORD COPY"

ML10

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

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

24. PERSONNEL MONITORING DEVICES

TYPE <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	<input checked="" type="checkbox"/> FILM	Siemen Gammasonics, Inc.	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		
b. FINGER	<input type="checkbox"/> FILM		
	<input checked="" type="checkbox"/> TLD	Siemen Gammasonics, Inc.	Monthly
	<input type="checkbox"/> OTHER (Specify)		
c. WRIST	<input type="checkbox"/> FILM		
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		

d. OTHER (Specify)

Direct Reading Pocket Dosimeters (gamma) supplied by Atomic Products Corporation. Read and zeroed in weekly.

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 hereon, 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:

(2) LICENSE FEE ENCLOSED: \$

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)

(1) NAME (Type of Print)

RADHAKRISHNA V.C. KAMATH, M.D.

(2) TITLE

Chief, Nuclear Medicine Service

c. DATE

2/11/85

PRIVACY ACT STATEMENT

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

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

RADIATION SAFETY COMMITTEE

Committee's Duties and Responsibilities - Please refer to pages 33 and 34 of the Radiation Safety Manual.

Meeting Frequency - Semi-annually.

Name and Specialty of Each Committee Member -

Radhakrishna V.C. Kamath, M.D., Chairman	- Chief, Nuclear Medicine Service
Seymour Goldgraben, M.D.	Chief, Medical Service
Hilton Rodriguez, M.D.	Chief, Radiology Service
Representative from Management	
Representative from Nursing Service	
Henry N. Wagner, Jr., M.D.	Head, Divisions of Nuclear Medicine Radiological Health Sciences, Johns Hopkins University

TRAINING AND EXPERIENCE

Authorized Users - 1) Radhakrishna V.C. Kamath, M.D. - NRC License 19-07187-01
Board Certification - Nuclear Medicine - 1974
Board Certification - Radiology - 1973

2) Henry N. Wagner, Jr., M.D. - NRC License 19-07187-01
Board Certification - Nuclear Medicine - 1961

Radiation Safety Officer - Radhakrishna V.C. Kamath, M.D., NRC License 19-07187-01

INSTRUMENTATION

1. Survey Meters

a. Manufacturer's name: Eberline

Manufacturer's model number: G-M Survey Meter Mll. E140

Number of instruments available: 1

Minimum range: 0.1 mr/hr to 0.5 mr/hr

Maximum range: 10 mr/hr to 50 mr/hr

b. Manufacturer's name: Atomic Products Corp.

Manufacturer's model number: 069-701

Number of instruments available: 1

Minimum range: 0.1 mr/hr to 0.5 mr/hr

Maximum range: 10 mr/hr to 50 mr/hr

c. Manufacturer's name: Victoreen

Manufacturer's model number: Air Ionization Cahmer Mll. 740-F

Number of instruments available: 1

Minimum range: 0 mr/hr to 25 mr/hr

Maximum range: 0 mr/hr to 25,000 mr/hr

2. Dose Calibrator

Manufacturer's name: RADIX Corporation

Manufacturer's model number: 225 - Assay I Isotope, 226 - Isotron, 227 - Isocord

Number of instruments available: 1

INSTRUMENTATION
(Continued:)

3. Diagnostic Instruments

<u>Type of Instrument</u>	<u>Manufacturer's Name</u>	<u>Model No.</u>
Scintillation Camera	Technicare	Mdl. 438
Rectilinear Scanner	Union Carbide	Cleon Mdl. 760
Gamma Scintillation Counter (automatic)	Searle	Mdl. 1185
Gamma Scintillation Counter (manual with thyroid probe)	Atomic Development Corporation	Mdl. 111S2
Nuclear Computer System	Technicare	Mdl. 560

CALIBRATION OF INSTRUMENTS

Survey Meters - Daily checks of constancy using built-in check sources.
(226-Ra)

Calibration by manufacturer annually and following repair using 137-Cs.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

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

B. Sources Used for Instrument Accuracy and Constancy Tests

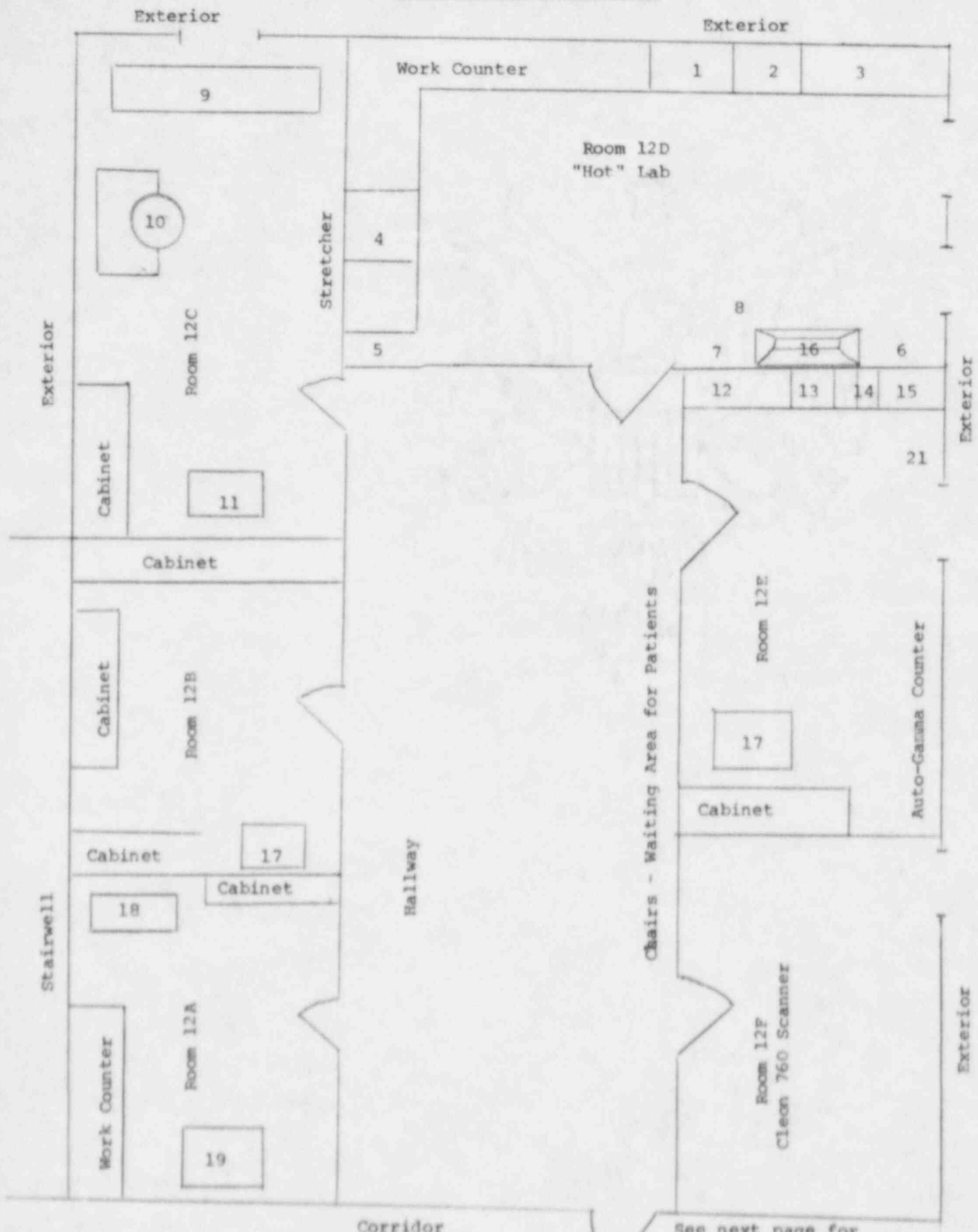
<u>Radionuclide</u>	<u>Activity (mCi)</u>	<u>Accuracy</u>
Co-57	5.3	<u>+4.5%</u>
Ba-133	.25	<u>+5%</u>
Cs-137	0.056	<u>+4.3%</u>

C. The Procedures described in Section 2 of Appendix D will be used for Calibration of the Dose Calibrator.

CALIBRATION OF INSTRUMENTS

The manufacturer's directions will be followed for calibration and maintenance of diagnostic instrumentation.

NUCLEAR MEDICINE SERVICE



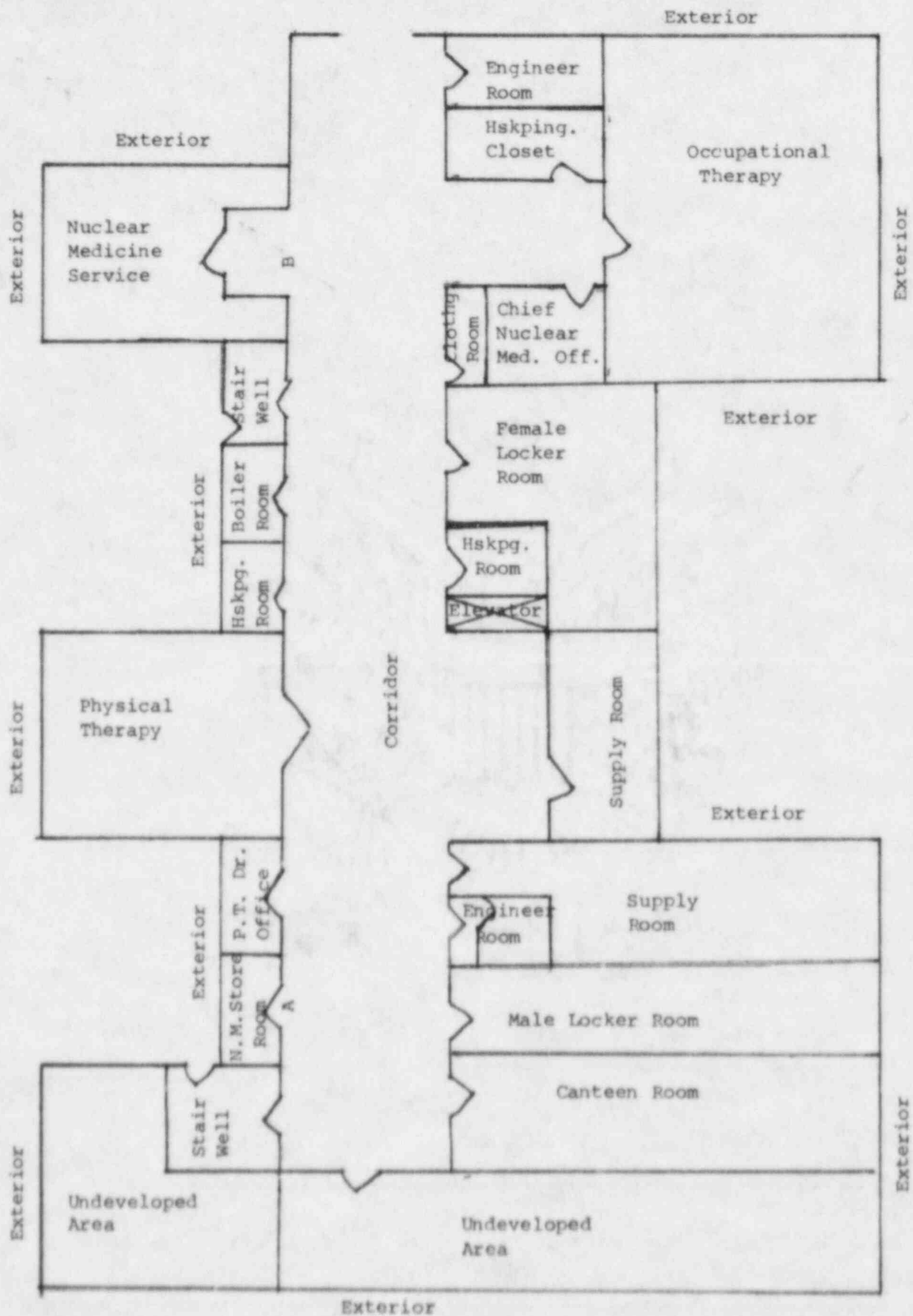
NUCLEAR MEDICINE SERVICE

Explanation of Numbers

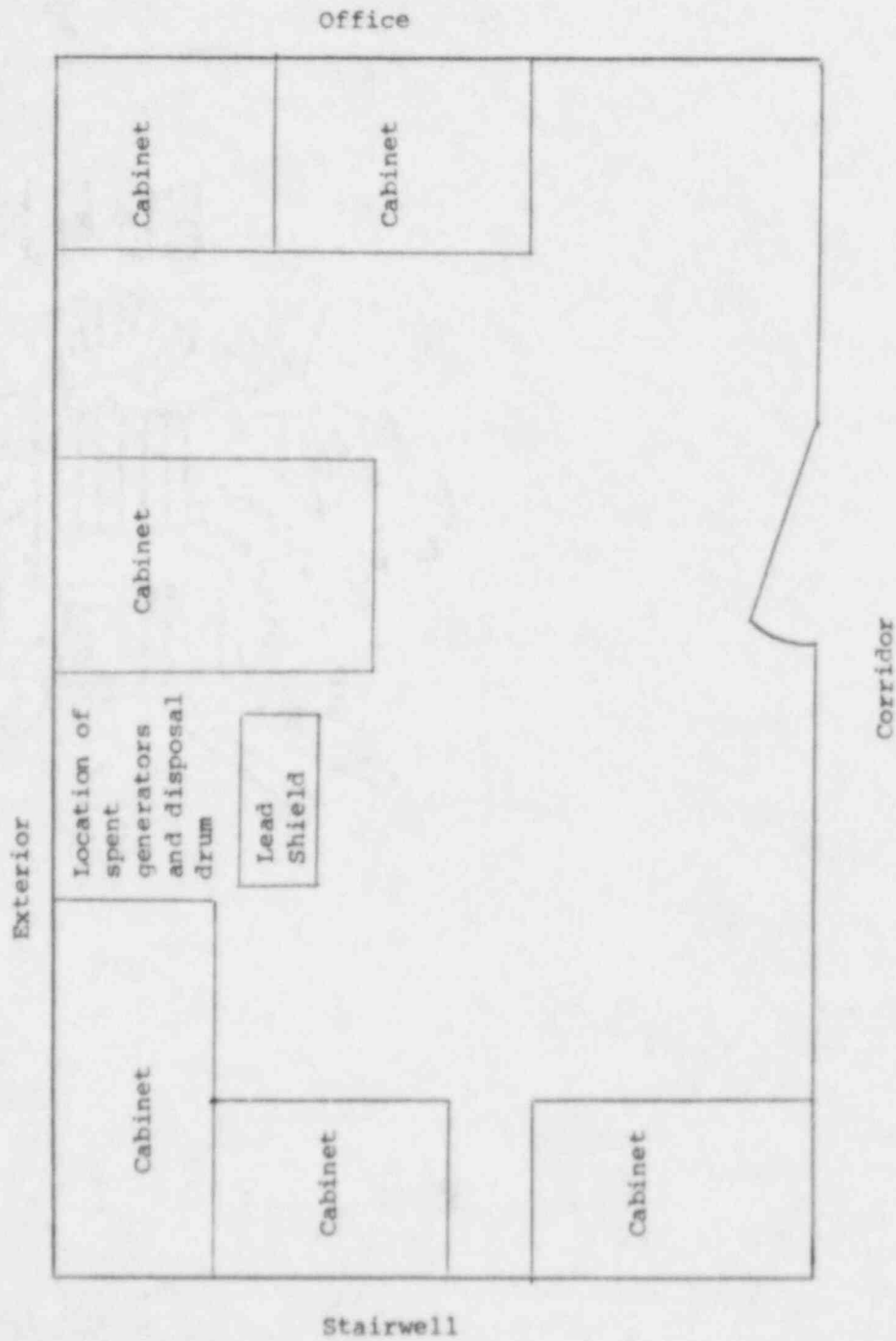
- 1 - Shield for Water Bath and Ultrasonic Mixer (sulfur colloid and albumin microspheres)
- 2 - Shield with lead glass - preparation of radiopharmaceuticals
- 3 - Shield for generators and all other radioactive materials
- 4 - "Hot" sink
- 5 - Trash can and soiled clothes
- 6 - Refrigerator for storage of perishable radiopharmaceuticals and radioimmunoassay kits
- 7 - Refrigerated centrifuge
- 8 - Table for blood-drawing
- 9 - Electronic console and Computer 560
- 10 - Head of Gamma Camera
- 11 - Technician's table
- 12 - Work Counter
- 13 - Sink
- 14 - Lead shield next to Dose Calibrator
- 15 - Dose Calibrator
- 16 - Fume Hood
- 17 - Technicians' tables
- 18 - Secretary's desk
- 19 - File cabinets
- 20 - Refrigerator
- 21 - Thyroid probe and Manual Well

BASEMENT BUILDING 19H

Distance between Point A and Point B is 110'.



NUCLEAR MEDICINE STORAGE ROOM



PERSONNEL TRAINING PROGRAM AND FREQUENCY

Technicians: Weekly in-service training and two (2) Extra-VA scientific conferences per year.

Other: Yearly lectures to Nursing personnel, Security personnel and Housekeeping Aids concerning Radiation Safety.

Records of the above are kept.

PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL

Please refer to Page 4 of the Radiation Safety Manual.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Please refer to Page 5 of the Radiation Safety Manual.

GENERAL LABORATORY RULES FOR THE SAFE USE OF RADIOACTIVE MATERIALS

Please refer to Pages 9 - 14 of the Radiation Safety Manual.

EMERGENCY PROCEDURES, INCLUDING NAMES AND TELEPHONE NUMBERS OF PERSONNEL
TO BE NOTIFIED

Please refer to Pages 14 - 17 of the Radiation Safety Manual.

A copy of the Emergency, Disaster and Civil Defense plans "Fan-Out"
is enclosed.

AREA SURVEY PROCEDURES

Please refer to Page 6 of the Radiation Safety Manual.

WASTE DISPOSAL PROCEDURES

Please refer to Page 18 of the Radiation Safety Manual.

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

Please refer to Pages 21 - 24 of the Radiation Safety Manual.

A patient who is treated with less than 30 mCi of ^{131}I is instructed concerning hydration, frequent voiding, reduction of absorbed radiation dose to others (distance and time), etc.

Only pre-calibrated capsules of ^{131}I are used in therapy. Containers holding therapeutic capsules (maximum possession limit - 50 mCi) are opened under the fume hood.

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

Please refer to Page 7 of the Radiation Safety Manual.