FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557

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

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

Department of the Army
Fitzsimons Army Medical Center
Denver, CO 80240

TELEPHONE NO.: AREA CODE 303 | 341 3826

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

Fitzsimons Army Medical Center
12101 East Colfax Ave.
Aurora, Colorado 80240

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Harry M. Cullings
Radiation Protection Officer
TELEPHONE NO. AREA CODE (303) 341 8960

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 05-00046-13
c. ☒ RENEWAL OF LICENSE NO. 05-00046-13

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

See item 4. attached.

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.)*

See item 5. attached.

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	1000
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	5000
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	2000

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	100
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	30
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	30
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	200
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	300
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	2000

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

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
See item 6. b. attached.			

A117

FORM NRC-313M (8-78)

7904210453

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Lexington-Bluegrass Army Depot	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	Contract request submitted	
		OTHER (Specify)		
c. WRIST	X	FILM	Lexington-Bluegrass Army Depot	Monthly
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: Exempt per 10CFR170.11

(2) LICENSE FEE ENCLOSED: $ None

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
PHILIP A. DEFFER, M. D.

(2) TITLE Brigadier General, MC
Commanding

c. DATE
MAR 6 1979

FORM NRC-313M (8-78)

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. 01 Date: Jan 79

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
X	Supplements A & B Attached for Each Individual User; and
X	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

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

Application for Renewal/Amendment of FAMC
NRC License 05-00046-13

CHANGES FROM THE 1974 LICENSE APPLICATION

The following changes have occured in the FAMC Radioisotope Program and Radiation Protection Program since a license application was last filed with the NRC. While some of the changes span all or part of the five year interim, a great many changes have been made and/or documented in recent months as an adjunct of applying for license renewal.

The changes are listed below in their order of appearance in the body of the application; they are keyed to the item numbers on NRC Form 313M.

Item 1. No change in addresses.

Item 2. Person to be contacted is the new Radiation Protection Officer, see Item 5.

Item 3. This application is both for renewal and for amendment. Regarding the requested amendment to a Specific License of Broad Scope; see Inclosure 2 to this letter of transmittal.

Item 4. The names of users have changed completely due to personnel turnover. All changes have been approved by the Radioisotope Committee and recorded. The most current list of users is attached to Item 4.

Item 5. A new RPO has been appointed. He is a full time RPO and has been put in charge of a Health Physics Section. This Section has been authorized a level of staffing that is in keeping with the recommendation of NUREG-0267 for the current size of the FAMC program: two RPO technicians and a part-time clerical worker.

Item 6. a. There have been several changes requested for possession limits here:

(1) The in vitro kits used under provisions of 10CFR35.11 have been assigned a total possession limit of 1000 mCi based on the large workload.

(2) Group III has been raised from 2000 to 5000 mCi due to considerably increased patient load.

(3) Group VI has been raised from 1000 to 2000 mCi due to increased patient load and increased inventory of sealed sources, particularly I-125 and Ir-192 seeds.

(4) Separately listed items from Groups IV and V have been assigned possession limits based on recommended dosages, patient load, and allowance for storage and decay.

9911[illegible]

Incl 1

Item 6. b. A requested possession limit has been added: 500 mCi of Mo-99/Tc-99m for state-of-the-art Nuclear Medicine uses as determined locally by the FAMC Radioisotope Committee. This corresponds directly with the amendment requested for a Broad License.

Item 7. The bylaws of the FAMC Radioisotope Committee as constituted in FAMC Reg 15-1 are being substantially revised to insure that the stated duties conform to Appendix B of Regulatory Guide 10.8.

Item 8. No Change.

Item 9. A considerable range of instrumentation has been added, especially survey instruments. See Item 9 for detail.

Item 10. No Change.

Item 11. The set of facilities diagrams has been greatly expanded and each diagram has an appended narrative description. Details pertinent to radiation protection are shown and/or described. New diagrams include:

(1) Detailed portions of Nuclear Medicine Service, including laboratory, injection room and camera rooms where Xe-133 is used.

(2) Additional in vitro use areas in Clinical Investigation Service.

(3) Health Physics Waste Lab.

(4) Storage area for sealed sources (Radiation Therapy Service).

(5) Clinical Pathology RIA Lab.

Item 12. The Personnel Training Program has been upgraded and better documented to assure compliance with 10CFR19.12 and other regulations, as reflected in Item 12.

Item 13. FAMC Reg 40-604, Appendix I Receipt, Transfer and Shipment of Radioactive Material has been updated.

Item 14. A Section I on safely opening packages containing radioactive materials has been added to the reference in Item 13 above.

Item 15. Control procedures for the use of radioisotopes (via Radioisotope Committee) have been strengthened and clarified, as reflected in Tab A.

General laboratory safety rules for handling radioisotopes have been augmented (Tab B).

In addition, a number of more specific procedures pertaining to radiation safety have been documented and added to the license to answer points of information raised in the Regulatory Guide 10.8; these are in Tabs C-F.

Item 16. The RPO has directed that emergency procedures to be instituted by users will be based on Appendix H of Regulatory Guide 10.8 and will embody all the features of that appendix.

Item 17. Health Physics area survey procedures have been changed to conform with those in Appendix I of Regulatory Guide 10.8. This included changing the frequency of formal surveys to weekly in areas where more than 100 microCi are used at one time.

Item 18. The disposal of waste has increased greatly in volume due to low level RIA waste from Clinical Pathology and Clinical Investigation Service.

The disposal program, however, is being given more thorough centralized management under the new Health Physics Section.

Item 19. Nursing aspects of patient care for unsealed sources have been made more complete, as reflected in Tab A.

Item 20. The statement in 19. above applies equally to sealed sources. In addition, handling procedures for sealed sources have been specifically documented as Tab A.

Item 21. Several studies have been done and the results have been used to calculate ventilation, gas trap efficiency and other parameters related to the use of Xe-133. A complete reply to Appendix M of Regulatory Guide 10.8, including a complete Standard Operating Procedure, has been submitted as Item 21.

Item 22. The program for use of radioactive materials in animals has been documented by writing a reply to Item 22 and a set of Instruction to Animal Caretakers. These are included as Item 22.

Item 23. For the first time a comprehensive Bioassay Program for the institution has been written, particular attention being given to Regulatory Guide 8.20. The program statement is included as Item 23.

Item 24. A contract request is being submitted for TLD ring badge service.

Justification for Requesting a Specific
License of Broad Scope (Type A)

The Nuclear Medicine Service at FAMC has grown considerably over the five years 1974 - 1979. Diagnostic equipment has been added, including a new mobile camera, large field camera, and computer. The staff has been augmented with a full-time radiopharmacist and has two physicians trained in Nuclear Medicine. The clinic occupies a newly remodeled and expanded facility.

It is felt that FAMC Nuclear Medicine Service would make an excellent Fellowship training site for nuclear medicine physicians, a site which the Army desperately needs. In order to have an effective Nuclear Medicine Fellowship Program, it is necessary to provide training in what is currently state-of-the-art nuclear medicine.

State-of-the-art applications are not possible if the license is confined to the procedures listed in Schedule A of 10 CFR 35.100. Rather, a Broad Scope License is needed so that the FAMC Radioisotope Committee may have the authority to locally approve new procedures. Such a license will also allow the formation of a research program for Fellowship purposes. In addition the Endocrine Fellowship will benefit by association with this research and the Clinical Investigation Service will be able to expand its program.

It should be noted that FAMC has the Radiation Protection resources to support this request. FAMC has recently constituted a Health Physics Section with a full time Radiation Protection Officer, two technicians, and a part-time secretary being authorized. All slots have been filled except for that of the junior technician, under requisition.

A new possession limit is being requested in conjunction with the request for a Broad License: 500 mCi of Mo-99/Tc-99m for uses as determined by the FAMC Radioisotope Committee. This possession limit is listed as paragraph H of Item 6.b.

Incl 2

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Item 15 General Rules for the Safe Use of Radioactive Material

Tab A Appendix A of FAMC Reg 40-604

Tab B Appendix B of FAMC Reg 40-604

Tab C Nuclear Medicine Standard Operating Procedure

(1) Preparation of Therapeutic Iodine Doses

(2) Opening of Sealed Containers

Clinical Investigation Service Standard Operating Procedure

(1) Iodination Procedure

Tab D Nuclear Medicine Standard Operating Procedure

(1) Preparation and Assay of Patient Doses

Tab E Standard Operating Procedure: Movement of Radioactive Materials

Tab F Appendix D of FAMC Reg 40-604

Item 18 Appendix J Form for Waste Disposal

Item 19 Therapeutic Use of Radiopharmaceuticals

Tab A Appendix P of FAMC Reg 40-604

Item 20 Therapeutic Use of Sealed Sources

Tab A Standard Operating Procedure: Handling of Sealed Radioactive Sources

Item 21 Procedures and Precautions for Use of Radioactive Gases (Xenon - 133)

Tab A Standard Operating Procedure: Xenon Studies

Tab B Manual for Xenon Lung Function Unit

Item 22 Procedures and Precautions for Use of Radioactive Materials in Animals

Tab A Instructions to Animal Caretakers

Item 23 FAMC Bioassay Program

ITEM 4

Individual Users

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

ITEM 4

Current List of Users

4. Names of Individual Users

Human Users will be board certified by the American Board of Radiology and/or the American Board of Nuclear Medicine. All users' credentials will meet the qualifications imposed by the NRC license provisions, 10 CFR, AR40-37, and FAMC Reg 40-604. Users' credentials will be approved by the FAMC Radioisotope Committee prior to their assuming duties.

Statements of training and experience, and preceptors' statements, where applicable, for current users are attached as Tab A of Item 8, listed in alphabetical order.

Following is a list of current users at FAMC:

Human Users - Supplement A & B enclosed.

AARESTAD, Norman O., M.D. (Civilian Contract Physician)
GHAED, Nasser, M.D., LTC, MC
RICHARDSON, David L., M.D. (Civilian Contract Physician)
TELEPAK, Robert J., M.D., MAJ, MC

Non-Human Users - Supplement A enclosed.

BETHENFALVAY, Nicholas, M.D., COL, MC
BROWN, George L., Ph.D., LTC, MSC
CHARLES, Merle A., M.D., Ph.D., LTC, MC
COGGIN, Julian T., M.D., COL, MC
HARBELL, John W., Ph.D., 1LT, MSC
NELSON, Harold, M.D., COL, MC
O'BARR, Thomas P., Ph.D., DAC, GS-13
ZOLOCK, David T., Ph.D., CPT, MSC

Special - Supplement A enclosed.

COLDREN, Lawrence E., MSPH, MAJ, MSC - Medical Physicist, Alternate RPO
ROTH, Eugene P., D.Ph., 1LT, MSC - Radiopharmacist

ITEM 5

Radiation Protection Officer

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

ITEM 5

Supplement A for Radiation Protection Officer

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
LT Harry M. Cullings RPO	N/A

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
N/A		

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	Lehigh University, Bethlehem, PA Acad. Health Sci, U. S. Army Fitzsimons Army Medical Center	120	 40 100
b. RADIATION PROTECTION	Acad Health Sci, U. S. Army Fitzsimons Army Medical Center	40	 100
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Lehigh University Fitzsimons Army Medical Center	100	 50
d. RADIATION BIOLOGY	Lehigh University	48	
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Cs-137	50 mCi	Fitzsimons Army Med. Ctr.	6 months	Brachytherapy
I-125	100 mCi	Fitzsimons Army Med. Ctr.	6 months	Seed Implant
I-131	150 mCi	Fitzsimons Army Med.Ctr.	6 months	Internal Dose

ITEM 6. b.

Radioactive Material for Uses
Not Listed in Item 6. a.

Renewal Application for FAMC NRC License
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Item 6. b. Radioactive Materials for Uses Not Listed in Item 6. a.

Element and Mass Number	Chemical and/or Physical Form	Maximum Number of Millicuries of Each Form	Purpose of Use
A. Iodine 131	A. Thyroxine	A. 2 mCi	A. Determination of Thyroxine turnover
B. Iodine 125	B. Thyroxine	B. 1 mCi	B. Determination of Thyroxine turnover
C. Cesium 137	C. Any	C. 1 mCi	C. Standard for assay of molybdenum content of eluate of molybdenum generator.
D. Any byproduct material with Atomic Nos. 1-83, inclusive	D. Any	D. 500 mCi each, except: Hydrogen-3 - 5000 mCi. Total not to exceed 10,000 mCi.	D. Laboratory research <u>in vitro</u> and in lower animals, <u>in vitro</u> testing.
E. Xenon 133	E. Free gas or in saline	E. 2000 mCi	E. Pulmonary function studies. Blood flow studies.
F. Hydrogen 3	F. Water	F. 25 mCi	F. Determination of total body water.
G. Sodium 24	G. Sodium chloride	G. 1 mCi	G. Determination of total exchangeable sodium.
H. Molybdenum-99/Technetium-99m generators for the elution of Technetium-99m as pertechnetate	H. Pertechnetate	H. 500mCi	H. For human diagnostic uses as determined by the FAMC Radioisotope Committee.

ITEM 7

FAMC Radioisotope Committee

Renewal Application for FAMC NRC License
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7. Medical Isotopes Committee

The FAMC Radioisotope/Radiation Control Committee is established in accordance with Army Regulation 40-37. Following are the current members and their specialties/positions:

Nasser Ghaed, LTC, MC, Chief, Department of Radiology, Chairperson

Julian Coggin, COL, MC, Chief, Department of Pathology

Lewis A. Mologne, COL, MC, Chief, Department of Surgery

George W. Ward, COL, MC, Chief, Department of Medicine

Donald G. Corby, COL, MC, Chief, Clinical Investigation Service

Michael L. Johnson, LTC, MSC, Chief, Central Purchasing Division (Non-voting)

Lawrence E. Coldren, MAJ, MSC, Medical Physicist, Department of Radiology, Radiation Therapy Service, Asst. Radiation Protection Officer

Robert J. Telepak, MAJ, MC, Chief, Nuclear Medicine Service, Department of Radiology

Harry M. Cullings, 2LT, MSC, OIC, Health Physics Section, Preventive Medicine Activities

ITEM 8

Training and Experience of Users

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

Tab A

ITEM 8

Supplements A and B for Current Users

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

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AINI_ AND EXPERIENCE OF HUM_ ERS

USING PHYSICIAN'S NAME, RANK, SERVICE NUMBER, DUTY ASSIGNMENT, DUTY EXTENSION

Dr. Norman O. Aarestad
CIV
SSN
Dept RadiationTherapy
Fitzsimons AMC Denver CO 80240
341-8801 341-3045

CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) Maximum Activity Used	(D) No. Cases Observed (See Key 1 below)	(E) No. Cases Involving personal participation (Key 2)
I–131 or I–125	DIAGNOSIS OF THYROID FUNCTION	[illegible]	50	40
	DILUTION STUDIES		5	3
	EXCRETION STUDIES			
	BRAIN TUMOR LOCALIZATION			
	SCANNING STUDIES		10	8
	TREATMENT OF HYPERTHYROIDISM		5	3
	TREATMENT OF CARDIAC CONDITIONS		1	
	TREATMENT OF THYROID CARCINOMA		2	1
P–32 Soluble	TREATMENT OF POLYCYTHEMIA		2	1
	TREATMENT OF LEUKEMIA		10	2
	TREATMENT OF BONE METASTASES	21 mCi	10	10
	TUMOR LOCALIZATION	700 µCi	75	50
	INTRACAVITARY TREATMENT		10	2
	INTERSTITIAL TREATMENT			
Au–198	INTRACAVITARY TREATMENT		3	1
	INTERSTITIAL TREATMENT			
	SCANNING STUDIES		2	1
Cr–51	BLOOD DETERMINATIONS			
	SCANNING STUDIES			
Co–58 or Co–60	DIAGNOSIS OF PERNICIOUS ANEMIA		5	2
Co–60 Ir–192	INTERSTITIAL TREATMENT		15	13
	INTRACAVITARY TREATMENT			
Co–60 or Cs–137	TELETHERAPY TREATMENT	9000 Ci	5 2000	1500
Sr–90 Sr–85	TREATMENT OF SUPERFICIAL DISEASES OF THE EYE		100	20
	BONE SCAN			
Other Isotopes Use back of page	I-125 - interstitial prostate	25 mCi	24	23

Key to Columns (D) and (E) above

1. *Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.*
2. *Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.*

DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING	DATE	HOURS
	1960 - 63	3 - 4 months

The training and experience indicated above was obtained under the supervision of Dr. T. Fulcher & C. V. Allen

Univ of Oregon, Portland — 28 June 77 — Norman O. Aarestad

(Name and Address of Institution) (Date of Signature) (Signature of Applicant)

FAMC FORM 4229-X
1 APR 75

TRAINING AND EXPERIENCE OF PRINCIPAL USERS OF RADIOISOTOPES

NAME AND RANK: Dr. Norman O. Aarestad

DATE: 27 Jun 77

TYPE TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Check)		FORMAL COURSE (Check)	
			YES	NO	YES	NO
1. Principles and practices of radiation protection						
2. Radioactivity measurement standardization and monitoring techniques and instruments						
3. Mathematics and calculations basic to the use and measurement of radioactivity						
4. Biological effects of radiation						

EXPERIENCE WITH RADIATION (*Actual Use of Radioisotopes or Equivalent Experience*)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
226 Ra.	ca 200 mg.	Univ. of Oregon	1 yr	Human
	ca 400 mg	WRAIR	2 yr	"
222 Rn.	10 m Ci.	WRGH, LGH, & St. Lukes	10 yr.	"
192 Ir.		WRGH	2 yr.	"
131 I		Univ of Ore.	1 yr.	"
59 Fe		Univ. of Ore & WRAIR	14 mos	Human & experimental
54 Mn		WRAIR	1 yr	Experimental
14 C		WRAIR	1 yr	"
32 P		WRAIR, St. Lukes,	7 yr	Human & experimental
	(over)			

20 F	WRAIR.	1 yr	experimental.
40 K	WRAIR	1 yr	"
51 Cr	Limit of Det	1 yr	human
64 Co	WRAIR.	1 yr	experimental.
198 Au	Limit of Det.	1 yr	human
137 Cs	WRGH, LGH, St. Lukes.	10 yr	"
60 Co	WRAIR, WRGH, St. Lukes.	8 yr.	" + experimental
90 Sr	Limit of Det, WRAIR & WRGH	12 yrs	human + "
Ionization Reaction	WRAIR.	1 yr	"
125 I	St. Lukes.	1 1/2 yrs.	human.

TRAINING AND EXPERIENCE OF PRINCIPAL USERS OF RADIOISOTOPES	NAME AND RANK: Aarestad, [illegible] O. MAJ			DATE: 11 Dec 6[illegible]	

TYPE TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Check) YES	ON THE JOB (Check) NO	FORMAL COURSE(S) YES	FORMAL COURSE(S) NO
1. Principles and practices of radiation protection	1) Radiology Residency Univ. of Oregon (1960-63) 2) Univ. of Rochester, M.S. (1965-66)	3 yrs 1 yr.	X		X X	
2. Radioactivity measurement standardization and monitoring techniques and instruments	1) Univ. of Oregon 2) Univ. of Rochester	3 months 6 months	X X		X X	
3. Mathematics and calculations basic to the use and measurement of radioactivity	1) Univ. of Oregon 2) Univ. of Rochester	3 yrs. 1 yr.	X X		X X	
4. Biological effects of radiation	1) Univ. of Oregon 2) Univ. of Rochester	2 months. 1 yr.	 X		X X	

EXPERIENCE WITH RADIATION (Actual Use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
226Ra	approx. 300 mg. [illegible]	Univ. of Oregon.	1 yr.	Human
	approx. 400 mg. [illegible]	WRGH	3 mos.	"
222Rn	≤ 10 mCi	WRGH	3 mos.	"
192Ir		WRGH	"	"
131I		Univ. of Oregon.	"	"
59Fe		Univ. of Oregon + WRAIR.	1½ "	" + expen.
54Mn		WRAIR	1½ "	experimental
14C		WRAIR	1½ "	"
32P		WRAIR	1½ "	"
	(mice)			

WRAMC FORM [illegible]

^{20}F	WRAIR	12 months	experimental
^{40}K	WRAIR	"	" + human
^{51}Cr	Univ. of Oregon	"	human
^{64}Cu	WRAIR	"	experimental
^{198}Au	Univ. of Oregon	12 months	human
^{137}Cs	WRGH	3 "	human
^{60}Co	WRAIR + WRGH	15 "	human + experimental
^{90}Sr	Univ. of Oregon, WRAIR + WRGH	27 "	" + experimental
Nuclear Reactor	WRAIR	12	experimental

TRAINING AND EXPERIENCE OF HUMAN USERS
(CR 40-10)

1. USING PHYSICIAN'S NAME, RANK, SERVICE NUMBER, DUTY ASSIGNMENT, DUTY EXTENSION

NORMAN O. AAKESTAD, MAJOR OF 106643.
FELLOW IN RADIOTHERAPY EXT 3575

2. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 1 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) NO. CASES OBSERVED (See 1 in Key Below)	(D) NO. CASES INVOLVING PERSONAL PARTICIPATION (See 2 in Key Below)
I-131	Diagnosis of thyroid function	50	40
	Dilution studies	5	3
	Excretion studies		
	Brain tumor localization		
	Scanning studies	10	8
	Treatment of hyperthyroidism	5	3
	Treatment of cardiac conditions	1	
	Treatment of thyroid carcinoma	2	1
P-32 Soluble	Treatment of polycythemia	2	1
	Treatment of leukemia	10	2
	Treatment of bone metastases	2	1
	Tumor localization		
	Intracavitary treatment		
	Interstitial treatment		
Au-198	Intracavitary treatment	3	1
	Interstitial treatment		
	Scanning studies	2	1
Cr-51	Blood determinations		
	Scanning studies		
Co-58 or Co-60	Diagnosis of pernicious anemia	5	2
Co-60 I-192	Interstitial treatment	1	1
	Intracavitary treatment		
Co-60 or Cs-137	Teletherapy treatment	150	50
Sr-90	Treatment of superficial diseases of the eye	15	7
Other Isotopes Use back of page			

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration technique and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

3. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING 3-4, [illegible], [illegible]

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF: DR. T. HUGHES & DR. C.H. ALL

UNIV. OF OREGON, AT PORTLAND, OREGON (Institution, Name and Address)

11 Dec 62 (Date of Signature)

Norman O. Aakestad (Signature of Applicant)

TRAINING AND EXPERIENCE OF PRINCIPAL USERS OF RADIOISOTOPES

NAME AND RANK: Bethenfalvay, Nicholas COL

DAT: 20 Oct 75

TYPE TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Check) YES	ON THE JOB (Check) NO	FORMAL C (Check) YES	FORMAL C (Check) NO
1. Principles and practices of radiation protection	Nuclear Emergency Team Course Kirtland AFB, Alburquerque, N.M.	2 wks	X		X	
2. Radioactivity measurement standardization and monitoring techniques and instruments	NET Course as in (1.) above	2 wks	X		X	
3. Mathematics and calculations basic to the use and measurement of radioactivity	University of Omaha	1 semester			X	
4. Biological effects of radiation	NET Course as in (1.) above	2 wks			X	

EXPERIENCE WITH RADIATION *(Actual Use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{59}FE	10 microcuries	University of Colorado Medical Center (Division of Hematology)	October 1968-July 1970	in vitro

FAMC FORM 4230-X

FORM NRC-313M SUPPLEMENT A
(8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR ~~RADIATION SAFETY OFFICER~~	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
GEORGE L BROWN, Ph.D	None

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Academy of Microbiology - Immunology Specialty; Pathologist Bacteriology	—	June 1974

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	University of Rhode Island Sept 62 - Jan 63	100	40
b. RADIATION PROTECTION	Medical Field Service School (Ft Sam Houston) Oct 61	24	—
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	University of Rhode Island Sept 55 - Jun 56 Sept 62 - Jan 64	100	—
d. RADIATION BIOLOGY	University of Rhode Island Sept 62 - Jan 63	35	—
e. RADIOPHARMACEUTICAL CHEMISTRY	—	—	—

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Thymidine methyl-3-H	2 m C	University of Rhode Island	2 yrs	Laboratory
I 131	10 m C	Fitzsimons Army Medical Center	5 yrs	Laboratory
Chromium 51	406 C	" " "	6 months	Laboratory

TRAINING AND EXPERIENCE OF PRINCIPAL USERS OF RADIOISOTOPES

NAME AND RANK: M.A. Charles, LTC, MC

DATE: 28 June 77

TYPE TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Check) YES	ON THE JOB (Check) NO	FORMAL COURSE (Check) YES	FORMAL COURSE (Check) NO
1. Principles and practices of radiation protection	Univ. of Calif at Irvine	1 semester		x	x	
	Univ of Calif at Irvine	2 years	x			x
	Univ. of Calif at San Francisco	4 Years	x			x
	Letterman AMC	2 years	x			x
2. Radioactivity measurement standardization and monitoring techniques and instruments	As above	1 semester		x	x	
		2 years	x			x
		5 years	x			x
		2 years	x			x
3. Mathematics and calculations basic to the use and measurement of radioactivity	As above	"	"	"	"	"
4. Biological effects of radiation	University of Calif at Irvine	1 semester		x	x	

EXPERIENCE WITH RADIATION *(Actual Use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{14}C, ^{3}H	500 uCi	Los Angeles State College	2 yrs	Laboratory
^{14}C, ^{3}H	500 uCi	U. C. Irvine	2 yrs	"
^{125}I, ^{14}C, ^{3}H		U.C. San Francisco	5 yrs	"
^{125}I, ^{14}C, ^{3}H		Letterman Army Med. Center	2 yrs	"

TRAINING AND EXPERIENCE OF PRINCIPAL USERS OF RADIOISOTOPES

NAME AND RANK: JULIAN T COGGIN, LTC, MC

DATE: 27 Jun 77

TYPE TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Check) YES	ON THE JOB (Check) NO	FORMAL COURSE (Check) YES	FORMAL COURSE (Check) NO
1. Principles and practices of radiation protection	Dept of Pathology & ALS Fitzsimons Army Medical Center	6 months	X			
	Squibb Seminar in Radioisotopes Denver. Colorado May 1977	5 days			X	
2. Radioactivity measurement standardization and monitoring techniques and instruments	Dept of Pathology & ALS Fitzsimons Army Medical Center	6 months	X			
	Squibb Seminar in Radioisotopes Denver, Colorado May 1977	5 days			X	
3. Mathematics and calculations basic to the use and measurement of radioactivity	Dept of Pathology & ALS Fitzsimons Army Medical Center	6 months	X			
	Squibb Seminar in Radioisotopes Denver, Colorado May 1977	5 days			X	
4. Biological effects of radiation	Loma Linda University, 1957-58 Loma Linda, California, Radiation Physiology	6 months			X	
	Dept of Pathology & ALS Fitzsimons Army Medical Center	6 months	X			

EXPERIENCE WITH RADIATION *(Actual Use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I^{125}		Department of Pathology & ALS Fitzsimons Army Medical Center	6 months	In-vitro
Co^{57}		Department of Pathology & ALS Fitzsimons Army Medical Center	6 months	In-vitro
Fe^{59}		Department of Pathology & ALS Fitzsimons Army Medical Center	6 months	In-vitro

FAMC FORM 4230-X

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER & Medical Physicist	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Lawrence E. Coldren	N/A

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
N/A	N/A	N/A

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	UNC Chapel Hill,N.C. 1970-1972	192 hrs	128 hrs
b. RADIATION PROTECTION	Kirkland AFB, N.M. 1975 UNC Chapel Hill,N.C. 1970-1972	96 hrs	160 hrs
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	UNC Chapel Hill,N.C. 1970-1972	129 hrs	64 hrs
d. RADIATION BIOLOGY	UNC Chapel Hill,N.C. 1970-1972	96 hrs	30 hrs
e. Radiation Therapy Physics ~~XXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXX XXXXXXXX~~	UNC Chapel Hill,N.C. 1970-1972 M.D. Anderson Hosp. Houston, Texas Jan 1977	160 hrs	1900 hrs

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Co-60	10,000Ci	UNC & Fitzsimons AMC	3 years	Research & Clinica
Ra-226	400mCi	UNC	1 year	Research
Cs-137	370mCi	Fitzsimons Army Med.Ctr.	2 years	Clinical
Ir-192	200mCi	Fitzsimons Army Med. Ctr.	2 years	Clinical
Sr-90	100mCi	Fitzsimons Army Med.Ctr	2 years	Clinical
Tc-99m	1.5Ci	Fitzsimons Army Med. Ctr.	6 months	Clinical
I-125	100mCi	Fitzsimons Army Med. Ctr	2 years	Clinical
I-131	100mCi	Fitzsimons Army Med. Ctr.	1 year	Clinical

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
NASSER GHAED, M.D., LTC, MC	Pennsylvania

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Nuclear Medicine Radiology		1974 1975

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	Fellowship at Walter Reed & Johns Hopkins March 72 - June 73	320	200
b. RADIATION PROTECTION	"	120	100
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	160	120
d. RADIATION BIOLOGY	"	100	40
e. RADIOPHARMACEUTICAL CHEMISTRY	"	160	160

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
See Preceptor Statement and main user from Sept 73 to present.		I have been Chief of Nuclear Medicine from Sept 73-July 78		

Form AEC-313
(2-73)
Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Page 2 may be used for comments and additional information.

10 NAME AND ADDRESS OF APPLICANT PHYSICIAN (Include ZIP Code)

Nasser Ghaed, M.D.
Dept of Radiology, Fitzsimons Army Medical Center, Denver, CO 80240

11 CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 10 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I-131 or I-125 or I-123	Diagnosis of thyroid function - Thyroid Uptake - I-123		6050
	Determination of blood and blood plasma volume / I-125		80
	Liver function studies - Rose Bengal I-131		25
	T3 and T4 I-125, T3 RIA		153,000
	ETR Test I-125		3,500
	Perchlorate Washout I-131 or I-123		260
Cr-51	Gastrointestinal protein loss studies		25
	Determination of red blood cell volume and studies of red blood cell survival		125
Fe-59	Iron turn over studies		25
Co-57	Intestinal absorption studies - Schilling Test		300
I-131	Thyroid - Whole Body Imaging		500
I-123	Thyroid imaging		2,000
I-131	Triolein Fat Absorption		10
In-111	Cisternography		75
Tn-111	Whole Body Imaging		20
Tc-99m	Cardiac Imaging		100
	Kidney imaging		350
I-131	Renogram		200
Cr-51	Placenta localization		
	Spleen imaging		10
Au-198	Liver imaging		
Hg-197	Brain imaging		
	Kidney imaging		25 100
Hg-203	Brain imaging		25
Sr-85	Bone imaging		50
Tc-99m	Brain imaging		6,300
	Thyroid imaging		200
	Salivary gland imaging		20
	Blood pool imaging		6,800

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
Tc-99m	Placenta localization		20
	Liver and spleen imaging		2300
	Lung imaging		1200
	Bone imaging		3500
Xe-133	Blood flow studies and pulmonary function studies		1050
Se-75	Pancreas imaging		25
P-32	Treatment of polycythemia, leukemia, and Bone metastases		125
	Intracavitary treatment		5
I-131	Treatment of thyroid carcinoma		50
	Treatment of hyperthyroidism and cardiac condition		200
Au-198	Intracavitary treatment		
I-131	Whole Body Counts (Thyroid CA Patients)		460
Tc-99m	Liver/Lung Imaging		60
Tc-99m	Parotid Imaging		20
Ga-67	Whole Body Imaging		200
F18	Bone Imaging		100

Key to Columns (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed, (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data, and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

12 DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING

13 THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF

AT Walter Reed Army Hospital and Fitzsimons Army Medical Center 05-00046-13

(Institution) Name and Address (Byproduct Material License Number) (Expiration Date)

FORM NRC-313M SUPPLEMENT A
(8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
1LT John W. Harbell MSC PhD	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	U of California Santa Cruz (S.C.)	1 h/w as part of larger course	3 h/w
b. RADIATION PROTECTION	U of Calif - S.C.	As part of training program for use of isotopes	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY	U of Calif S.C. and Berkeley	1 hour/w as part of larger course	3 h/w
e. RADIOPHARMACEUTICAL CHEMISTRY	U of Calif S.C.	as part of PhD research	

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
H^3	20 mCi/year as thymidine	U of Calif - Santa Cruz	6 years	In vitro - autoradiography + tracer use
^{14}C	1 mCi/year	U of Calif Santa Cruz	6 years	In Vitro
I	[illegible]	U of Calif - Santa Cruz	1 year	[illegible] surface protein labeling

FORM NRC-313M SUPPLEMENT A
(8-78)

U.S. NUCLEAR REGULATORY COMMISSIO

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Nelson, Harold	Ga, Fla, Calif, Colo

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Internal Medicine Allergy-Immunol Recertified		1963 1970 1977

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	6 weeks during Int Med Residency in Isotope Clinic + 2 years experience in lab during Allergy-Immun Fellowship		
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{125}I		Univ of Michigan	2 years	lab
		TAMC	5 years	Lab

TRAINING AND EXPERIENCE OF PRINCIPAL USERS OF RADIOISOTOPES

HAROLD S. NELSON, COL, MC — 9 May 75

TYPE TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Check)		FORMAL COURSE (Check)	
			YES	NO	YES	NO
1. Principles and practices of radiation protection	Letterman Army Med Center, San Francisco, CA 6-week rotation thru Radioisotope Clinic during medical residency.	6 weeks	X			X
2. Radioactivity measurement standardization and monitoring techniques and instruments						
3. Mathematics and calculations basic to the use and measurement of radioactivity						
4. Biological effects of radiation						

EXPERIENCE WITH RADIATION (Actual Use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Various		Letterman Army Medical Center, Radioisotope Clinic, 1961	6 weeks	
Various		University of Michigan Medical Center	2 years	Measurement of lymphocyte blast transformation

AMEDD&S FORM 4230-X

FORM NRC-313M SUPPLEMENT A
(8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
O'Barr, Thomas P., PhD. DAC (SS-13)	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

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	Practical experience ranging from building a geiger counter to following developing instrumentation		
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Master's Research program - Dr Thompson GE Company - Hanford,	8 semester hours -	Lab & Lecture
d. RADIATION BIOLOGY	Washington		
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{65}Zn	millicurie	(1) Master's thesis U of Texas (Austin)	1950 - 1951	(1) Animal uptake
^{90}Sr, Y	millicurie	(2) A.E.C. Project - U of Texas (Austin)	1950 - 1951	(2) Uptake by algae for controlling fission products
^{14}C, ^{32}P	microcurie, millicurie	(3) PhD thesis, U of Texas	1952 - 1955	(3) Radioactive metabolites
		(4) Employed Human Nutrition Research, Beltsville, MD	1955 - 1965	(4) Metabolic studies
^{14}C	microcurie	(5) US Army Medical Research	1965 - 1971	(5) Metabolic studies
^{14}C	microcurie	(6) and Nutrition Laboratory [illegible]	1971 - 1979	(6) [illegible], metabolic [illegible]
[illegible]	microcurie + millicurie	(7) GTE, [illegible]		

TRAINING AND EXPERIENCE OF PRINCIPAL USERS OF RADIOISOTOPES

NAME AND RANK: Dr. David L. Richardson, Civ.

DATE: 27 Jun 77

TYPE TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Check) YES	ON THE JOB (Check) NO	FORMAL COURSE (Check) YES	FORMAL COURSE (Check) NO
1. Principles and practices of radiation protection	(1) Univ. of Oklahoma Medical Center	4 yr	X		X	
	(2) Oak Ridge Assoc Universities	2 wk.			X	
2. Radioactivity measurement standardization and monitoring techniques and instruments	(1) Univ. of Oklahoma Medical Center	4 yr	X			
	(2) Oak Ridge Assoc. Universities	2 wk	X		X	
3. Mathematics and calculations basic to the use and measurement of radioactivity	(1) Univ. of Oklahoma Medical Center	4 yr	X		X	
	(2) Oak Ridge Assoc. Univ.	2 wk.			X	
4. Biological effects of radiation	Univ. of Oklahoma Medical Center	4 yr	X		X	

EXPERIENCE WITH RADIATION (Actual Use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{226}Ra	approx 200 mg	Univ. of Oklahoma Med Center	4 yr.	Intracav. tx, Parenteral
^{131}I	approx. 100 mCi	Univ. of Oklahoma Med Center	4 yr.	Intrac tx,
^{198}Au	100 mCi	Univ. of Oklahoma Med Center	4 yr.	" "
^{32}P	15 mCi	Univ. of Oklahoma Med Center	4 yr	External
^{60}Co	approx 6000 Ci	Univ. of Oklahoma Med Center	4 yr	ALL HUMAN

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE ~~MEDICINE~~ Pharmacy
Roth, Eugene P.	Calif. & Nevada

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Certified Nuclear Pharmacist	By Letterman Army Medical Center	March 1975

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	US Naval Nuclear Pwr School	300	400
	Univ of the Pacific SEP 75 - DEC 75 JAN 67-68	6	16
	LAMC JAN-MAR 76	18	20
	Donner Lab, UC Berkeley MAR 76 - JULY 78	6	30
b. RADIATION PROTECTION	US Naval Nuclear Pwr School	100	100
	UOP	3	16
	LAMC	9	20
	Donner Lab, UCB	4	8
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	USN Nuc Pwr Sch	30	30
	UOP	6	16
	LAMC	4	8
	UCB	10	20
d. RADIATION BIOLOGY	USN Nuc Pwr Sch	30	30
	UOP	3	8
	LAMC	5	45
	UCB	20	10
e. RADIOPHARMACEUTICAL CHEMISTRY	UOP	30	80
	LAMC	20	280
	UCB	15	1000

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

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

E.P.Roth

Form NRC 313M Supplement A

Attachment I

Isotope	Max Amount	Where exp. gainde	Duration of exp.	Use
C-11	1 Curie	LBL, UC Berk.	1 yr	Research
N-13	15 Curies	"	8 mo.	"
F-18	200 mCi.	"	2 wks.	"
Na-22	5 mCi.	"	3 days.	"
Fe-52	100 mCi	"	2 wks	"
Zn-62	50 mCi	"	3 wks	"
Zn-65	2 mCi	"	4 Days	"
Ga-67	50 mCi	LAMC	6 mo.	Scanning
Ga-68	25 mCi	LBL, UC Berk	1 yr	Research
Ge-68	25 mCi	"	1 yr	"
Rb-82	20 mCi	"	3 yr	"
Rb-85	20 mCi	"	1 mo	"
Sr-82	50 mCi	"	3 yr	"
Sr-85	20 mCi	"	1 mo	"
Mo-99	1 Curie	"	4 yr	"
		LAMC		Scanning
Tc-99m	2 Curies	LBL, LAMC, FAMC	4 yr	"
In-111	15 mCi	LBL	3 days	Research
In-113	100 mCi	"	2 wks	"
Xe-133	1 Curie	LAMC	6 mo	"
I-123	5 mCi	LAMC, FAMC	1 yr	Scanning
I-131	100 mCi	"	1 yr	"
Tl-201	5 mCi	FAMC	6 mo	"

FORM NRC-313M-SUPPLEMENT A
(8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
ROBERT J. TELEPAK MD MAJ MC	CALIF. AND COLORADO

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
AMER. BOARD INTERNAL MEDICINE	BOARD CERTIFIED	JUNE, 1977
AMER. BOARD NUCLEAR MEDICINE	BOARD ELIGIBLE	will take EXAM SEPT 79

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	JUNE 76 - JUNE 79 2 YR NUCLEAR MEDICINE FELLOWSHIP LETTERMAN ARMY MED CTR.	120	40
b. RADIATION PROTECTION	SAFE USE + HANDLING OF ISOTOPES LAMC NOV, 76 RADIATION MANAGEMENT COURSE KIRTLAND AFB, NM	50 35	20 8
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Same as a. above	75	25
d. RADIATION BIOLOGY	Same as a. above	50	25
e. RADIOPHARMACEUTICAL CHEMISTRY	Same as a. above	50	50

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
all	preceptors	statement submitted Sept 78 when I was approved by radioisotope committee as a principal user	R. Telepak MD	

TRAINING AND EXPERIENCE OF HUMAN USERS

(FOR USE OF THIS FORM, [illegible] AMC PAM 40-34)

USING PHYSICIAN'S NAME, GRADE, SOCIAL SEC[illegible]TY NO., DUTY ASSIGNMENT, DUTY EXTENSION

ROBERT J. TELEPAK, LTC, MC
NUCLEAR MEDICINE SERVICE
Fitzsimons Army Medical Center
Denver, Colorado

	CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN		
(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) NO. CASES OBSERVED (See 1 in key below)	(D) NO. CASES INVOLVING PERSONAL PARTICIPATION (See 2 in key below)
I-131 or I-125	Diagnosis of thyroid function	1373	1373
	Determination of blood and blood plasma volume	73	73
	Liver function studies	16	16
	Fat absorption studies		
	Kidney function studies	524	524
	In vitro studies	See attached RIA Procedures	
Cr-51	Gastrointestinal protein loss studies		
	Determination of red blood cell volume and studies of red blood cell survival	73	73
Fe-59	Iron turnover studies	2	2
Co-58 or Co-60	Intestinal absorption studies		
K-42	Potassium space determinations		
I-131 OR I-123	Thyroid imaging	1373	1373
	Brain tumor localization and scanning		
	Cisternography		
	Lung imaging		
	Liver imaging	524	524
	Kidney imaging		
	Placenta localization		
Tc-99m	Pulmonary perfusion		
	Spleen imaging		
Au-198	Liver imaging		
Hg^{203}-197	Brain imaging		
	Kidney imaging		
Hg^{203}-203	Brain imaging		
S-35	Bone imaging		
	[illegible]		

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) NO. CASES OBSERVED (See 1 in key below)	(D) NO. CASES INVOLVING PERSONAL PARTICIPATION (See 2 in key below)
Tc-99m	Placenta localization		
	Liver and spleen imaging	2248	2248
	Lung imaging	631	631
	Bone imaging	4435	4435
Xe-133	Blood flow studies and pulmonary function studies	611	611
Se-75	Pancreas imaging	17	17
P-32	Treatment of polycythemia, leukemia, and Bone metastases	3	3
	Intracavitary treatment		
I-131	Treatment of thyroid carcinoma	12	12
	Treatment of hyperthyroidism and cardiac condition	42	42
Au-198	Intracavitary treatment		
Co-60 or CO-137	Interstitial treatment		
	Intracavitary treatment		
Ir-192	Interstitial treatment		
Co-60 CO-137	Teletherapy treatment		
Sr-90	Treatment of eye disease		

KEY TO COLUMNS (C) AND (D) ABOVE

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data, and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

Dates and total number of hours of clinical radioisotope training 1 JULY 76 to 30 JUNE 78 4160 HRS

The training and experience indicated above was obtained under the supervision of [illegible] J. HILL, M.D., LTC, MC

99158

APPLICATION FOR BYPRODUCT MATERIAL LICENSE – MEDICAL

SUPPLEMENT [illegible] – HUMAN USE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
Tc-99m	Placenta localization		
	Liver and spleen imaging	2448	2448
	Lung imaging	631	631
	Bone imaging	4435	4435
Xe-133	Blood flow studies and pulmonary function studies	611	611
Se-75	Pancreas imaging	17	17
P-32	Treatment of polycythemia, leukemia, and Bone metastases	3	3
	Intracavitary treatment		
I-131	Treatment of thyroid carcinoma	12	12
	Treatment of hyperthyroidism and cardiac condition	42	42
Au-198	Intracavitary treatment		
Co-60 or CO-137	Interstitial treatment		
	Intracavitary treatment		
I-137	Interstitial treatment		
Co-60 CO-137	Teletherapy treatment		
Sr-90	Treatment of eye disease		

Key to Column (C) and (D) above

1. Observation should consist of [illegible] discussion with preceptor the case histories to establish most appropriate diagnostic [illegible] etc.

2. Personal participation should [illegible] and recommendation of dosage [illegible] including calculation of the radiation dose, related measurements and plotting of data, and [illegible] adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

12. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING

13. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF Robert J. Lull, M.D., LTC, MC
C, Nuclear Medicine Service
Letterman Army Medical Center
Presidio of San Francisco, CA 94129

Isotope	Conditions Diagnosed Or Treated	No. Cases Observed	No. Cases Involving Personnel Participant
^{99m}Tc	Kidney Imaging	758	758
	Biliary Imaging	34	34
	Esophageal Motility	18	18
	Cardiac Pools and Shunts	108	108
	Bone Marrow Imaging	3	3
	Lymph Node Imaging	1	1
	Intracardiac Shunt Quantitation	15	15
	Gated Cardiac Imaging	44	44
	Arterial Leg Perfusion Imaging 6	6	6
	Testicular Imaging	24	24
^{67}Ga	Whole-Body Imaging	365	365
	Brain Imaging	6	6
^{201}Tl	Cardiac Imaging	389	389
^{111}In	Bone Marrow Imaging	1	1
	Cisternogram	33	33
	CSF Shunt Function Study	4	4
Co^{57}	Schilling's Test	33	33

RIA PROCEDURES

	1976	1977	1978	TOTAL
HAA	4388	3351	2312	10,051
B-12	2247	2057	2406	6,710
CEA	1746	2515	2648	6,909
Cortisol		1446	1422	2,868
Estriol		1124	1450	2,574
Folic Acid	2247	2221	2362	6,830
Digoxin	2138	2460	3408	8,006
TSH	2350	3465	2925	8,740
T-3	1813	6961	5617	14,391
T-4	1813	7003	5736	14,552
T-3 RIA		1145	416	1,561
Gentamiacin			624	624
Amakacin			175	175
Pregnancy			681	681
Thyroid Profile			12474	12,474
Ferritin			38	38

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U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
David T. Zolock, PhD	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Penn State University	4	
	Letterman Army Inst. of Research	8	>40
b. RADIATION PROTECTION	Penn State University	4	
	Letterman Army Inst. of Research	8	> 40
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Penn State University	8	
	Letterman Army Inst. of Research	8	> 40
d. RADIATION BIOLOGY	Letterman Army Inst. of Research	8	
e. RADIOPHARMACEUTICAL CHEMISTRY	Letterman Army Inst. of Research	8	

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{14}C	7 mCi	Pennsylvania State University Letterman Army Inst. of Res.	5 years 4 years	Laboratory "
^{3}H	5 mCi	PSU LAIR	5 years 4 years	" "
^{125}I	10 mCi	LAIR	4 years	"
^{32}P	2 mCi	LAIR	4 years	"
^{45}Ca	5 mCi	LAIR	4 years	"
^{47}Ca	2 mCi	LAIR	4 years	"
^{35}S	2 mCi	LAIR	4 years	

ITEM 9

Instrumentation

Renewal Application for FAMC NRC License
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TYPE OF INSTRUMENT	NUMBER AVAILABLE		RADIATION DETECTED	SENSITIVITY RANGE	WINDOW THICKNESS	USE
	INS	PROBE				
VICTOREEN SCINTILLATION SURVEY METER MODEL 490	2	1	VICTOREEN Gamma Beta	PROBE Above 6KeV Above 200KeV	489-4 20mg/cm2	Monitoring and Survey
		1	VICTOREEN Alpha	PROBE Above 4MeV	702 3mg/cm2 6" dia crystal	
EBERLINE PORTABLE LIN-LOG GAS PROPORTIONAL ALPHA COUNTER PAC 4G3	2		AC21 Probe Alpha	0-500000 cpm	0.85 mg/cm2	Monitoring and Survey
			AC 21B Probe Beta	0-500000 cpm	0.85 mg/cm2	
	INS	PROBE				
EBERLINE PORTABLE BETA-GAMMA SURVEY METER MODEL E120	4	4	HP 190 Probe Beta/Gamma	0-50 mR/hr	1.4-2mg/cm2	Monitoring and Survey
		1	HP 210 Probe Beta	0-50 mR/hr	1.4-2 mg/cm2	
VICTOREEN PANORAMIC SURVEY METER MODEL 470A	1		Alpha Beta Gamma	0-1000 R/hr	17.0 mg/cm2	Monitoring and Survey
EBERLINE RADIATION MONITOR MODEL RM-14	1		HP 190 Probe Beta Gamma	0-50000 cpm	1.4-2 mg/cm2	Room Monitor

TYPE OF INSTRUMENT	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE	WINDOW THICKNESS	USE
VICTOREEN SURVEY METER MODEL 666	1	Background Probe Gamma/X-ray	3 mR-300 R/hr	220 mg/cm2	Survey
		Diagnostic Probe Gamma/X-ray	30mR-30,000R/hr	220 mg/cm2	
VICTOREEN SURVEY MODEL 440	1	Alpha Beta X-ray	0-300 mR/hr	3.0 mg/cm2	Survey
VICTOREEN CONDENSOR	INS 2 PROBE 1	VICTOREEN Gamma X-ray	CHAMBER 2.5R High Energy	552 ~~N/A~~ * 561 mg/cm²	Survey
	2	VICTOREEN Gamma X-ray	CHAMBER 25 Medium Energy	70-5 ~~N/A~~ * 67 mg/cm²	
	1	VICTOREEN Gamma X-ray	CHAMBER 5 Medium Energy	228 ~~N/A~~ * 212 mg/cm²	
	2	VICTOREEN Gamma X-ray	CHAMBER 100 Medium Energy	131 ~~N/A~~ * 89 mg/cm²	
	2	VICTOREEN Gamma X-ray	CHAMBER 100 High Energy	621 ~~N/A~~ * 576 mg/cm²	
	1	VICTOREEN Gamma X-ray	CHAMBER 250 Low Energy	651 ~~N/A~~ * 6.6 mg/cm²	

* nominal wall thichness

TYPE OF INSTRUMENT	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE	WINDOW THICKNESS	USE
PICKER TWINSCALER II WITH MAGNAWELL	1	Gamma	12.5 KeV-4 MeV	Sodium Iodide Crystal (Thallium Activated) 2"X2"	Sample Counting In-Vitro, Wipe Tests
PICKER AUTOWELL MODEL PACE I	1	Gamma	0.1-2.0MeV	Sodium Iodide (Thallium Activated) Thru-Hole 2"X2" Crystal	Sample Analysis/RIA/In-Vitro Studies Wipe Tests, 200 Sample Capacity
RADIAC METER AN/PDR27P CAROL ELECTRONICS	1	Beta Gamma	0-500 mR/hr	4.06 mg/cm2	Monitor and Survey
RADIAC METER AN/PDR27R CAROL ELECTRONICS	1	Beta Gamma	0-500 mR/hr	4.06 mg/cm^2	Monitor and Survey
PICKER ROOM MONITOR MODEL #600081	1	PICKER Beta Gamma	PROBE 0-30000 cpm	MODEL #610401 End window Not Used	Room Monitor
EBERLINE THEROLUMINESCENT DOSIMETER READER MODEL TLR-5	1	N/A	1mR-100000 R	N/A	Determination of Radiation Dose

TYPE OF INSTRUMENT	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE	WINDOW THICKNESS	USE
PACKARD INSTRUMENT AUTOMATIC WELL COUNTER MODEL 5360	1	Gamma	0-2000KeV	NaI Activated Thallium Quartz Window Crystal Thru-hole Design	Sample Analysis/RIA/In-Vitro Studies 600 Sample Capacity Crystal Diameter - 3"
PACKARD INSTRUMENT AUTOMATIC WELL COUNTER MODEL 5320	1	Gamma	0-2000KeV	Two NaI Activated Thallium Quartz Window Crystal Thru-hole	Sample Analysis/RIA/In-Vitro Studies 600 Sample Capacity Crystal Diameter - 3"
VICTOREEN RADOCON II MODEL 555	INS: 1 / PROBE: 1	VICTOREEN Gamma X-ray 400-1300KeV	PROBE 555-100Ha OmR/m-100R/m Integrate OR-10,000R	(High Energy) N/A	Monitor
	1	VICTOREEN Gamma X-ray 35-400KeV	PROBE 555-100mA OmR/m-1R/m Integrate OmR-10R	N/A	
	1	VICTOREEN Gamma Xray 35-400KeV	PROBE 555-100mA OmR/m-1000R/m Integrate OR-10,000R	N/A	
PICKER	1	Gamma	12.5KeV-4MeV	Sodium, Iodide Thallium Activated 2½"x 2½" Crystal Thru-hole	Sample Counting/RIA/In-Vitro Studies 100 Sample Capacity

TYPE OF INSTRUMENT	RADIATION DETECTED	ENERGY RANGE	CRYSTAL SIZE AND TYPE	NUMBER OF P. M. TUBES	USE
PICKER MAGNASCANNER II RECTILINEAR Scanner	Gamma	50-KeV-4MeV	Sodium Iodide Thallium Activated 3"x2"	1	Diagnostic Organ Scanning Primarily Thyroid
GENERAL ELECTRIC MAXISCAN DUAL PROBE RECTILINEAR SCANNER	Gamma	20-600KeV	2 Sodium Iodide Thallium Activated 5"x3"	2	Diagnostic Organ Scanning Primarily Bone Scanning
AMES LABORATORIES VOLEMATRON	Gamma	Automatic Cr-51 I-125 I-131	2 Sodium Iodide Thallium Activated 1"diameter Thru-hole	2	In-Vitro Blood and Plasma Volume Determination Portable
MICROMETIC SYSTEM CONCEPT-4 AUTOMATIC WELL COUNTER	Gamma	20-150KeV	2 Sodium Iodide Thallium Activated 2"x2" Thru-hole	2	In-Vitro Radioimmunoassay RIA
NUCLEAR CHICAGO (SEARLE)ULTRA SCALER II, MODEL 8276, WITH DUAL CHANNEL ANALYZER MODEL 8742	Gamma	25-1000KeV	Sodium Iodide Thallium Activated 2"x2"	1	Thyroid Uptakes and other organ Counting

TYPE OF INSTRUMENT	RADIATION DETECTED	ENERGY RANGE	CRYSTAL SIZE AND TYPE	NUMBER OF P.M. TUBES	USE
SEARLE PHO-GAMMA II GAMMA CAMERA	Gamma	50-680KeV	Sodium Iodide Thallium Activated 12"x½"	19	Diagnostic Organ Imaging Camera Room I
PICKER DYNACAMERA 3C GAMMA CAMERA	Gamma	44-662KeV	Sodium Iodide Thallium Activated 12"x½"	19	Diagnostic Organ Imaging Camera Room II
PICKER DYNACAMERA 415 GAMMA CAMERA	Gamma	50-680KeV	Sodium Iodide Thallium Activated 15"x½"	37	Diagnostic Organ Imaging Camera Room IV
OHIO NUCLEAR MOBILE CAMERA 120-GAMMA CAMERA	Gamma	50-200KeV	Sodium Iodide Thallium Activated 14.3"x½"	37	Diagnostic Organ Imaging Portable
PICKER-TWIN PROBE RENOGRAM MACHINE WITH DUALRATE COMPUTER DUAL DECADE SCALERS, AND DUAL CHANNEL ANALYZER	Gamma	50Kev-1MeV	2 Sodium Iodide Thallium Activated 3"x2" each	2	Diagnostic Renal Blood Flow Studies, and other Blood Flow Studies

TYPE OF INSTRUMENT	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE	WINDOW THICKNESS	USE
BECKMAN AUTO GAMMA COUNTER MODEL 8000	1	Gamma	0-2KeV	2" NaI Thru-Hole Crystal	Sample Analysis/RIA/In-Vitro Studies, Wipe tests, 200 Sample Capacity
BECKMAN AUTO GAMMA COUNTER MODEL LS 8100	1	Gamma	0-2KeV	2" NaI Thru-Hole Crystal	Sample Analysis/RIA/In-Vitro Studies, Wipe Tests, 200 Sample Capacity
PACKARD AUTO GAMMA COUNTER MODEL 587	1	Gamma	0-2MeV	3" NaI Thru-Hole Crystal	Sample Analysis/RIA/In-Vitro Studies, Wipe Tests, 300 Sample Capacity
PACKARD AUTO GAMMA COUNTER MODEL 5260	1	Gamma	0-2MeV	3" NaI Thru-Hole Crystal	Sample Analysis/RIA/In-Vitro Studies, Wipe Tests, 300 Sample Capacity
PACKARD TRI CARB LIQUID SCINTILLATION COUNTER	1	Beta Alpha	0-2MeV 0-2MeV	N/A	Sample Analysis/RIA/In-Vitro Studies, Wipe Tests, 300 Sample Capacity
PACKARD TRI CARB LIQUID SCINTILLATION COUNTER MODEL E3320 LS	1	Beta Alpha	0-2MeV 0-2MeV	N/A	Sample Analysis/RIA/In-Vitro Studies, Wipe Tests, 300 Sample Capacity

DOSE CALIBRATOR SPECIFICATIONS

TYPE OF INSTURMENT	ENERGY RANGE	ACTIVITY RANGE	USE
NUCLEAR CHICAGO (SEARLE) MEDIAC 6362 GAS IONIZATION CHAMBER	75 KeV - 3 MeV	0.05uCi - 99.9mCi (x10 for Tc - 99m)	Calibrations and assay patient doses
CAPINTEC CRC 6A	25 KeV - 3 MeV	0.1 uCi - 20 Ci	Calibrations and assay patient doses

ITEM 10

Calibration of Instruments

Renewal Application for FAMC NRC License
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26 February 1979

10. Calibration - Survey Instruments

Readings with a reference check source will be taken before and after use as described in Appendix D of Regulatory Guide 10.8.

Calibration will be done by Metrology Division, Sacramento Army Depot, Sacramento, Ca. (NRC License No's SNM507 and 04-04279-01) in accordance with Army Regulation 40-37.

AR 40-37 currently prescribes the following schedules for calibration:

USE	CALIBRATION SCHEDULE
Used directly in survey and monitoring	Every 3 months and after servicing/ repair
Pocket chambers and personnel dosimeters	Every 6 months
Used to measure exposure, dose or dose rate during therapy	Annually and after servicing/repair

ITEM 11

Facilities and Equipment

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

Item 11. Facilities and Equipment

1. Attached here as Tab A is a set of floor plans of locations at FAMC where radioactive materials authorized by NRC License 05-00046-13 will be used. Each plan is accompanied by a written description. The following areas are represented:

a. Nuclear Medicine Service - Floor plans # 1 -6, 6 A.

b. Health Physics Waste Lab - Floor plan # 7.

c. Clinical Investigation Service - Floor plans # 8 - 12, 12 A - D.

d. Radiation Therapy Service - Floor plan # 13.

e. Clinical Pathology RIA Lab - Floor plan # 14.

2. Therapy patients involving both sealed and unsealed sources are housed on appropriate wards in private isolated rooms in building 500, the main hospital. Rooms and surrounding areas are surveyed by the Radiation Protection Officer and approved by the Radiation Protection Officer and FAMC Radioisotope Committee before being used for these purposes.

3. Mobile camera scans will be performed on the wards in instances where the Chief of Nuclear Medicine deems it appropriate. In such cases the procedure in Tab E of Item 15 will be followed.

4. In accordance with the conditions of the license and Army Regulation 40-37, the FAMC Radioisotope Committee will be empowered to grant approval of additional facilities and equipment for uses of radioactive material. The Committee will act only after the Radiation Protection Officer has made a thorough survey of the proposed facility and provided the Committee with a documented recommendation.

ITEM 11

Facilities Diagrams

NUCLEAR MEDICINE SERVICE GENERAL FLOOR PLAN

1. Location - Building 511 West, 1st Floor

2. Adjoining Facilities

a. East - Post Library (limited access) - Doorway secured after duty hours.

b. West - Endocrinology Clinic (limited access) - Doorway secured after duty hours.

3. Entrance ways

a. Main Entrance - Waiting Room, secured after duty hours.

b. Elevator - secured with wire security screen after duty hours.

c. Hot Lab - fire exit only - no outside door latches. Inside has "panic bars".

d. North Entrance - located between Break Room and Rest Room - fire exit only - no outside door latches. Inside has "panic bars".

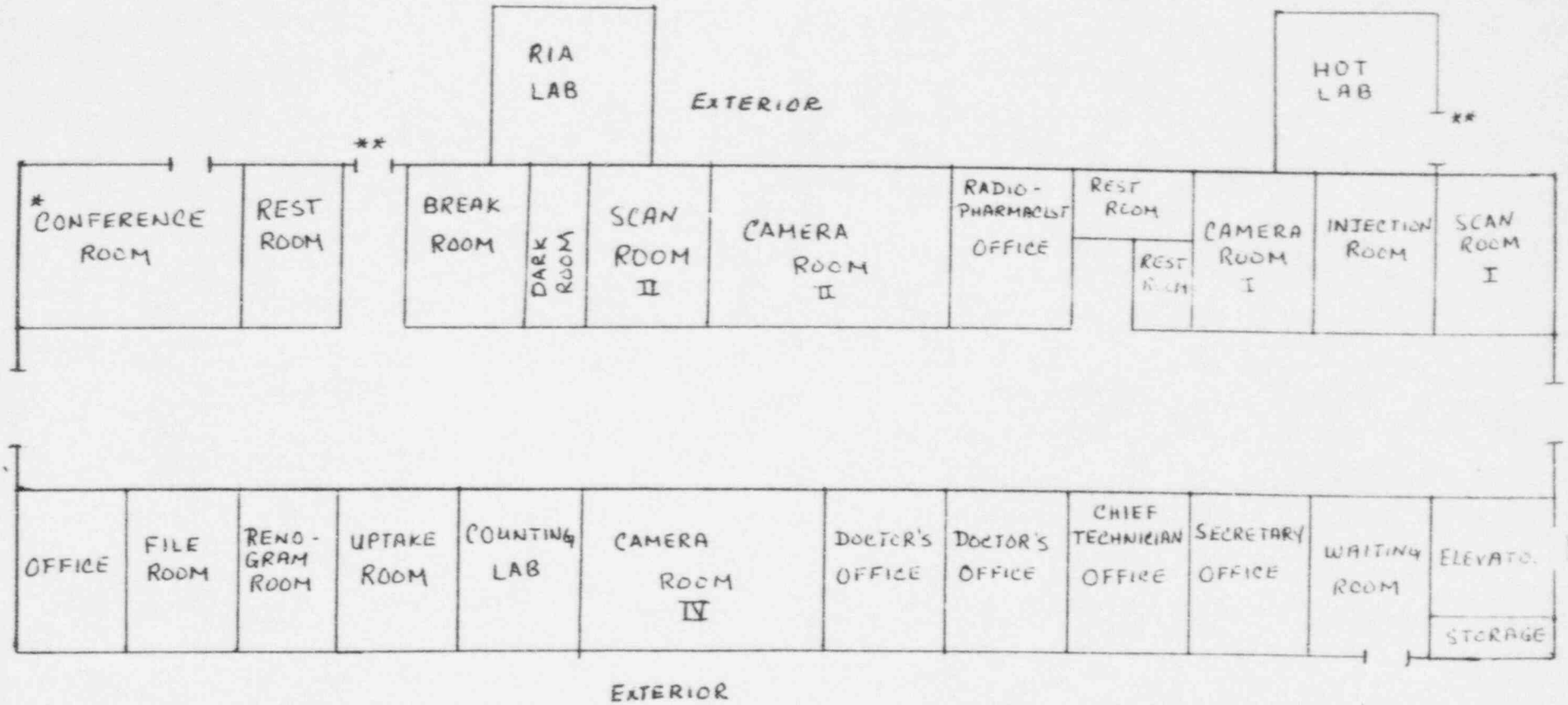
e. Conference Room - access from outside - secured after duty hours.

NUCLEAR MEDICINE SERVICE
BLDG 511W 1st FLOOR
FITZSIMONS ARMY MEDICAL CENTER

N

SCALE = 1 inch = 14FT

FLOOR PLAN *1



*FUTURE CAMERA ROOM

⊣ ⊢ INDICATES ENTRANCE

** FIRE EXIT ONLY
NO ACCESS FROM OUTSIDE

#1

NUCLEAR MEDICINE SERVICE HOT LAB

1. Location - Building 511 west, 1st floor.

2. Access - from injection room. Secured when unoccupied.

3. Description of Facilities (clockwise from door to injection room).

a. Refrigerator - (is not lead lined). Stor _ of non-radioactive radiopharmaceutical kits, chemicals, and low level radiopharmaceuticals (stored inside lead pigs).

b. Radioactive Waste - ½" lead lined wooden box with inner cardboard box and plastic bag. When full, the plastic bag is sealed, the cardboard box is removed, sealed, dated, and surveyed. After survey the box is labelled and transferred to Health Physics for disposal.

c. Work Bench #1 - Nuclear Chicago (Searle) Mediac 6362 Dose Calibrator.

d. Work Bench #2 - Capintec CRC6A Dose Calibrator.

e. Centrifuge - used for centrifugation of blood samples, and in-vitro radioactive samples.

f. Flood Source Storage - ½" lead lined - for storage of Co-57 Flood Field Check Sources.

g. In-vitro Work Bench and Cold Sink - for preparation of in-vitro laboratory tests.

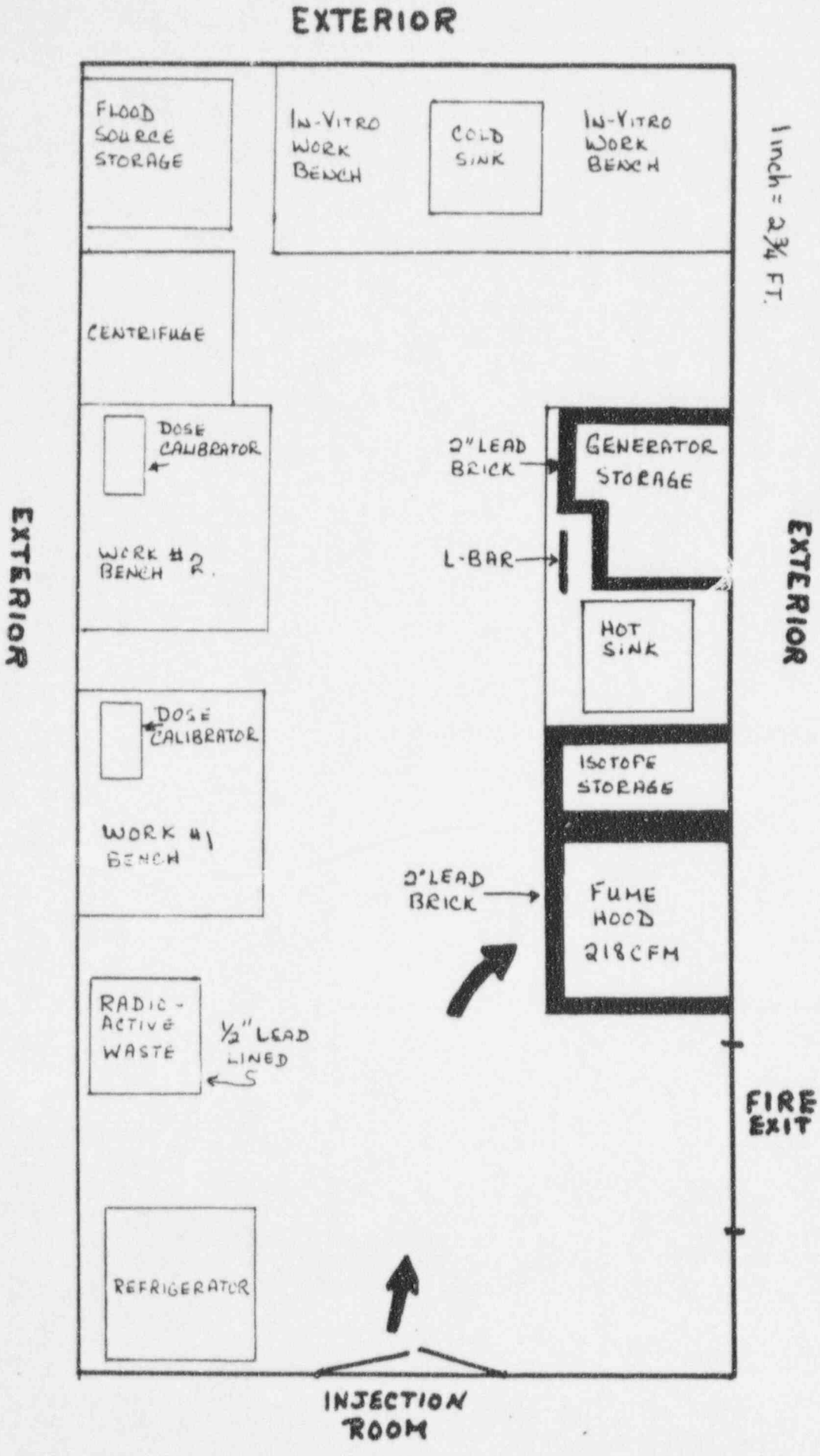
h. Generator Storage Area - protected by 2" lead bricks - storage of current and 1 week old Mo-99/Tc-99m Generators. L-Bar has 1" leaded glass shielding for preparation of radiopharmaceuticals.

i. Hot Sink - used for dumping liquid radioactive waste and decontamination of contaminated glassware.

j. Isotope Storage - protected by 2" lead bricks - used for storage of unexpired radiopharaceuticals.

k. Fume Hood - protected by 2" lead brick - air flow = 218 CFM. Used for preparation of radiopharmaceuticals and I-131 therapy dose preparation, storage of Xe-133 and other potentially volatile radioactive materials.

Nuclear Medicine Service
Hot Lab
Building 511W
FLOOR PLAN #2



INJECTION ROOM - NUCLEAR MEDICINE SERVICE

1. Location 511 west.

2. Use - administration of radiopharmaceuticals to patients.

3. Description of Facilities and Equipment - (refer to numbers on diagram)

a. (1) - Drug storage - contains non-radioactive drugs used for emergency treatment of patients.

b. (2) Injection Table - used for IV and oral administration of radiopharmaceuticals. Covered with absorbant pads.

c. (3) Supply Cabinet - storage of miscellaneous non-radioactive supplies.

d. (4 & 5) Picker Twinscaler II with Magnawell - used for in-vitro sample counting, counting of wipe tests, and student technician experiments.

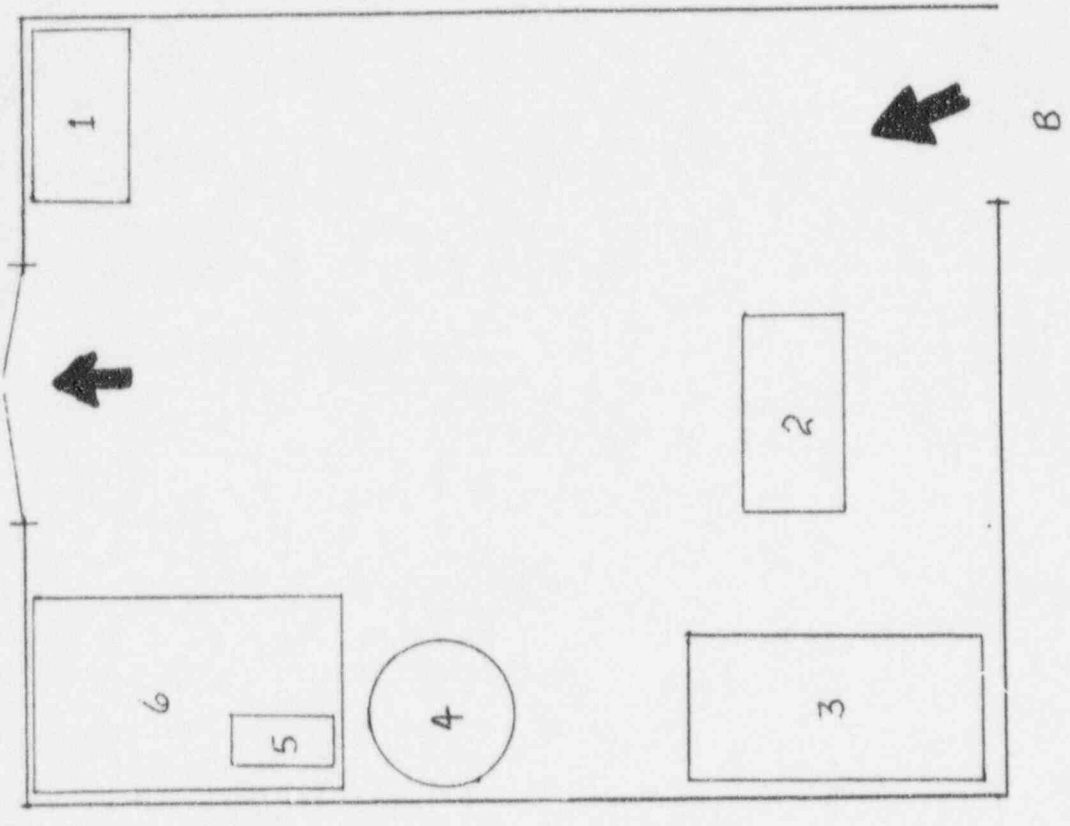
e. (6) Worktable

4. Air Flow - as indicated

1. Drug Sto e (Non-radioactive)
2. Injection Table
3. Supply Cabinet
4. Deep Well (Picker)
5. Scintillation Counter
6. Work Table

A. Entrance to Hot Lab
B. Entrance to Hallway

NUCLEAR MEDICINE SERVICE
Injection Room - Bldg 511W
FLOOR PLAN #3
SCALE: 1 inch = 3.2 FT



CAMERA ROOM 1 - NUCLEAR MEDICINE SERVICE

1. Location - building 511 west

2. Use - diagnostic thyroid whole body counting by use of open collimation, ventilation and perfusion lung imaging, and general back-up camera system.

3. Description of Equipment

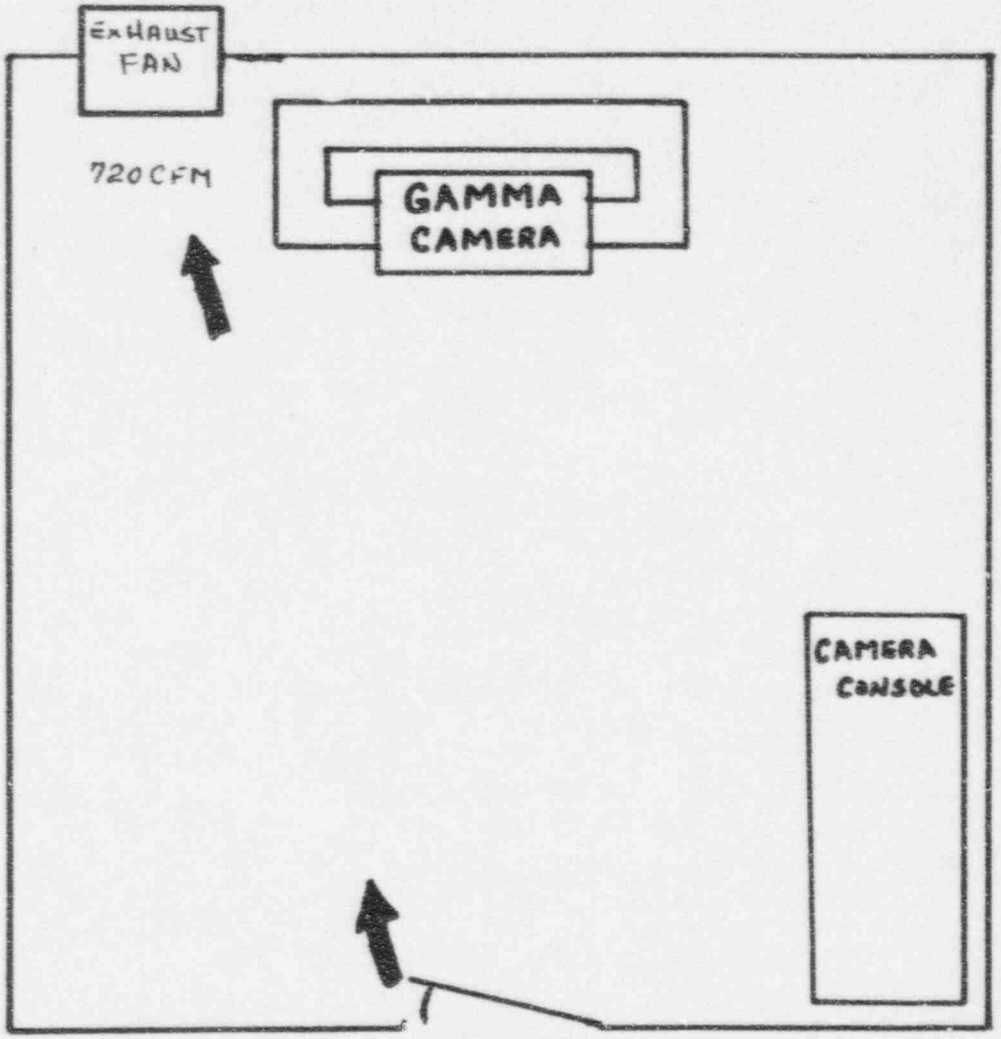
   a. Searle Pho-Gamma II Gamma Camera (Nuclear Chicago)

   b. Exhaust Fan - air flow measured at 720 CFM.

CAMERA ROOM 1
Nuclear Medicine Service
Building 511W
FLOOR PLAN # 4

SCALE = 1 inch = 2½ Ft.

EXTERIOR



HALLWAY

CAMERA ROOM 2 - NUCLEAR MEDICINE SERVICE

1. Location - building 511 west

2. Use - Diagnostic organ imaging including perfusion and ventilation lung imaging.

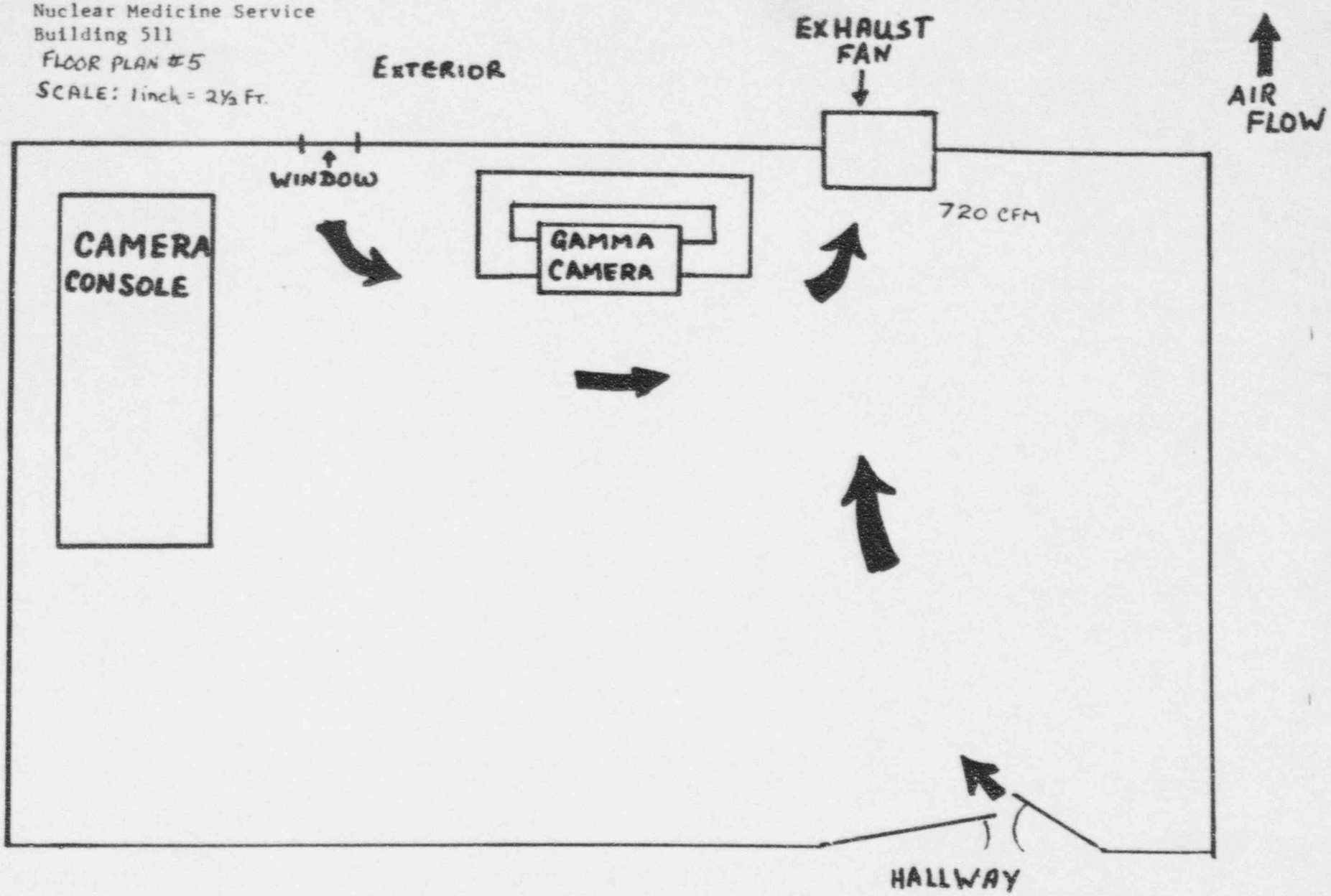
3. Equipment

a. Picker Dynacamera 3C Gamma Camera with moving table for bone images and computor capabilities (digital Electronics Model PDP 11e/05)

b. Exhaust Fan - air flow measured at 720 CFM.

4. Air Flow - as indicated

CAMERA ROOM 2
Nuclear Medicine Service
Building 511
FLOOR PLAN #5
SCALE: 1inch = 2⅓ FT.



CAMERA ROOM 4 - NUCLEAR MEDICINE SERVICE

1. Location - building 511 west

2. Use - Diagnostic organ imaging including perfusion and ventilation lung imaging.

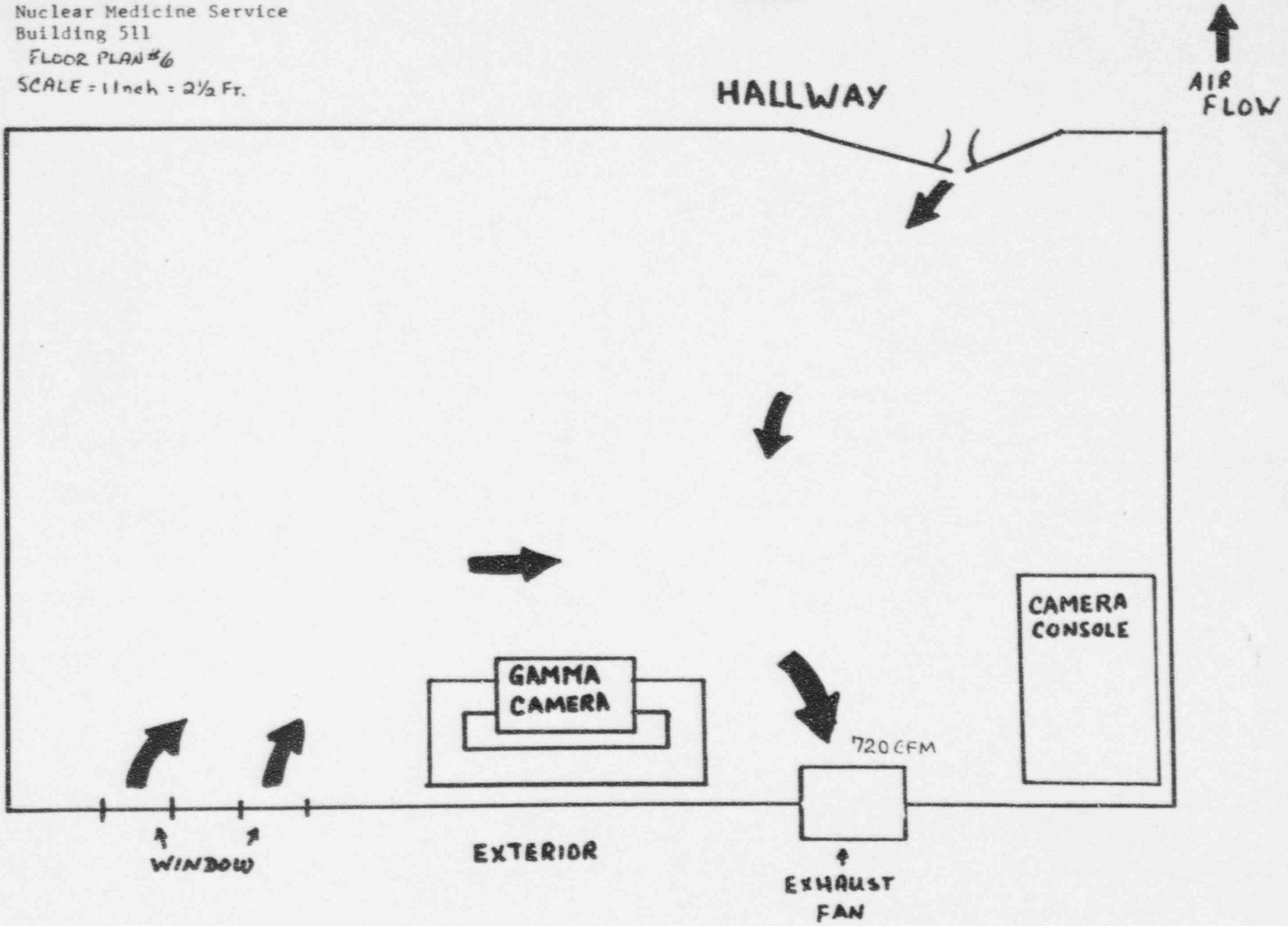
3. Equipment

a. Picker Dynacamera 415 - with moving table for bone images and interfaced with computor (Digital Electronics PDP 11e/05)

b. Exhaust Fan - air flow measured at greater than 2500 CFM.

4. Air Flow - as indicated.

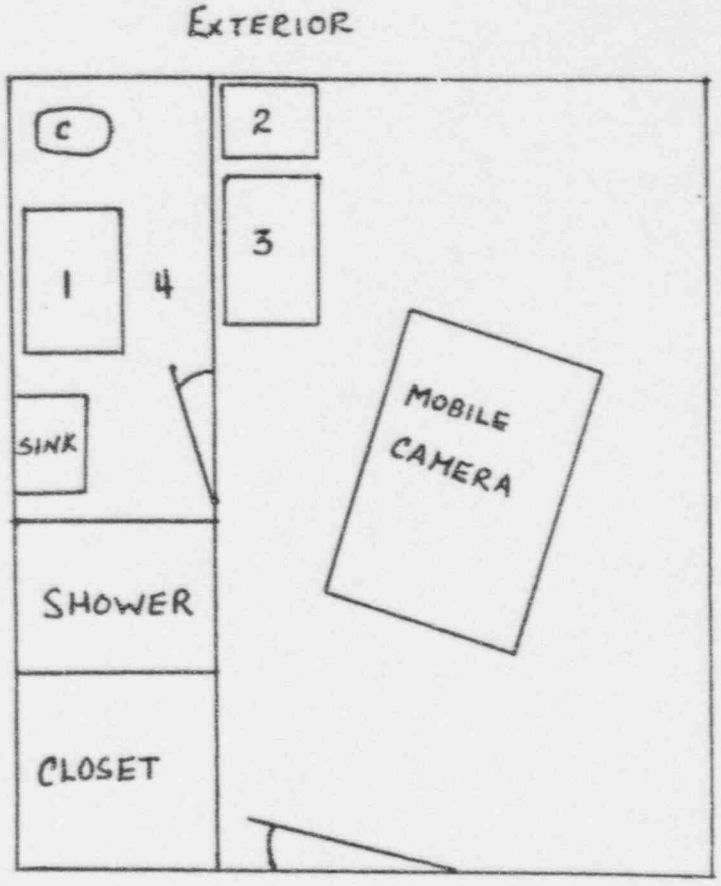
CAMERA ROOM 4
Nuclear Medicine Service
Building 511
FLOOR PLAN #6
SCALE = 1 inch = 2½ Ft.



MOBILE CAMERA ROOM
ROOM 4066 - 4TH FLOOR
BLDG 500 - FAMC
SCALE: 1 inch = 4 FT
FLOOR PLAN 6A

LEGEND:

1. COLLIMATOR CART
2. TAPE STORAGE
3. DESK
4. BATHROOM
C. COMMODE



WASTE LAB

1. Location - 1st floor building 603 east.

2. Use - storage and processing of radioactive waste for shipment to burial site, sink dumping.

3. Facilities

a. Fume Hood - provides ventilation (930 CFM) during waste preparation and while dumping liquid waste in hot sink. Has 1 inch lead lined isotope storage area.

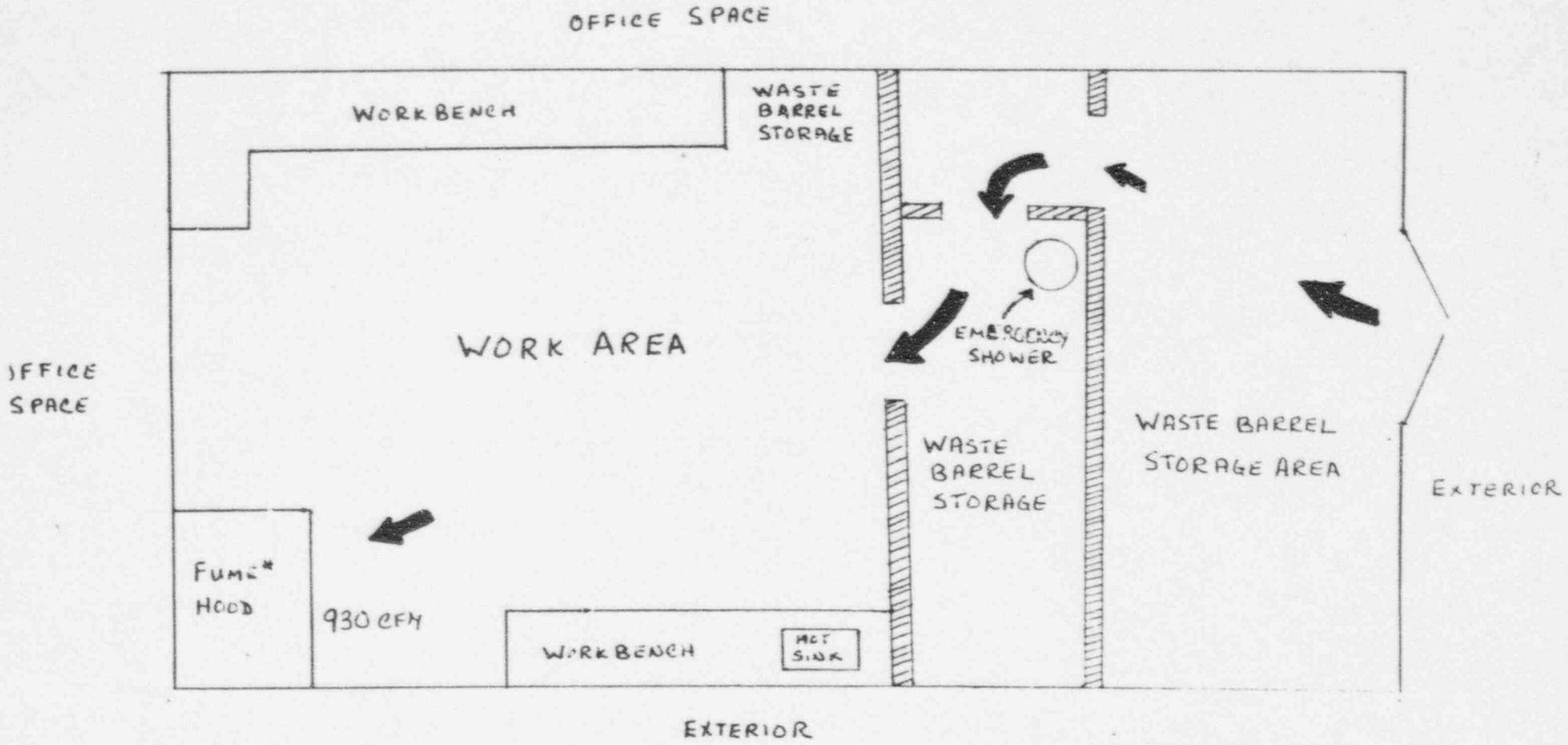
b. Hot Sink - used for disposal of liquid radioactive waste material.

c. Isotope Storage Area (lower level of Fume Hood) - used for storage of radioactive material for decay.

4. Air Flow - as indicated.

Waste Lab
Building 603-E FAMC
Scale: 1" = 5'
FLOOR PLAN #7

*Isotope storage area lower level fume hood
1" lead lined



OPEN LAB - CLINICAL INVESTIGATION SERVICE

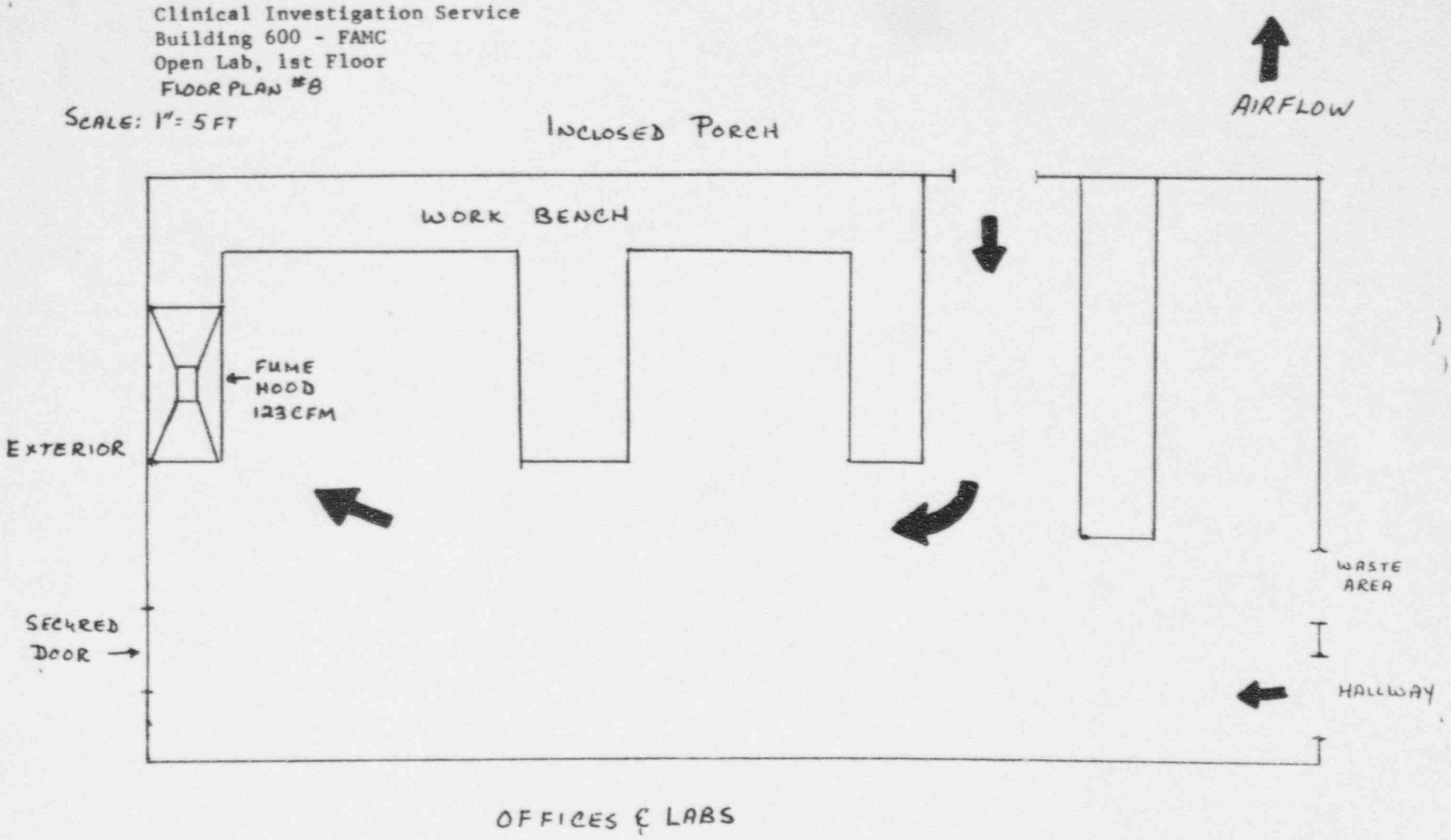
1. Location - Building 600, 1st floor.

2. Use - preparation of liquid scintillation samples.

3. Fume Hood and Air Flow Specification - as indicated.

Clinical Investigation Service
Building 600 - FAMC
Open Lab, 1st Floor
FLOOR PLAN #8

SCALE: 1" = 5 FT



OPEN LAB - CLINICAL INVESTIGATION SERVICE

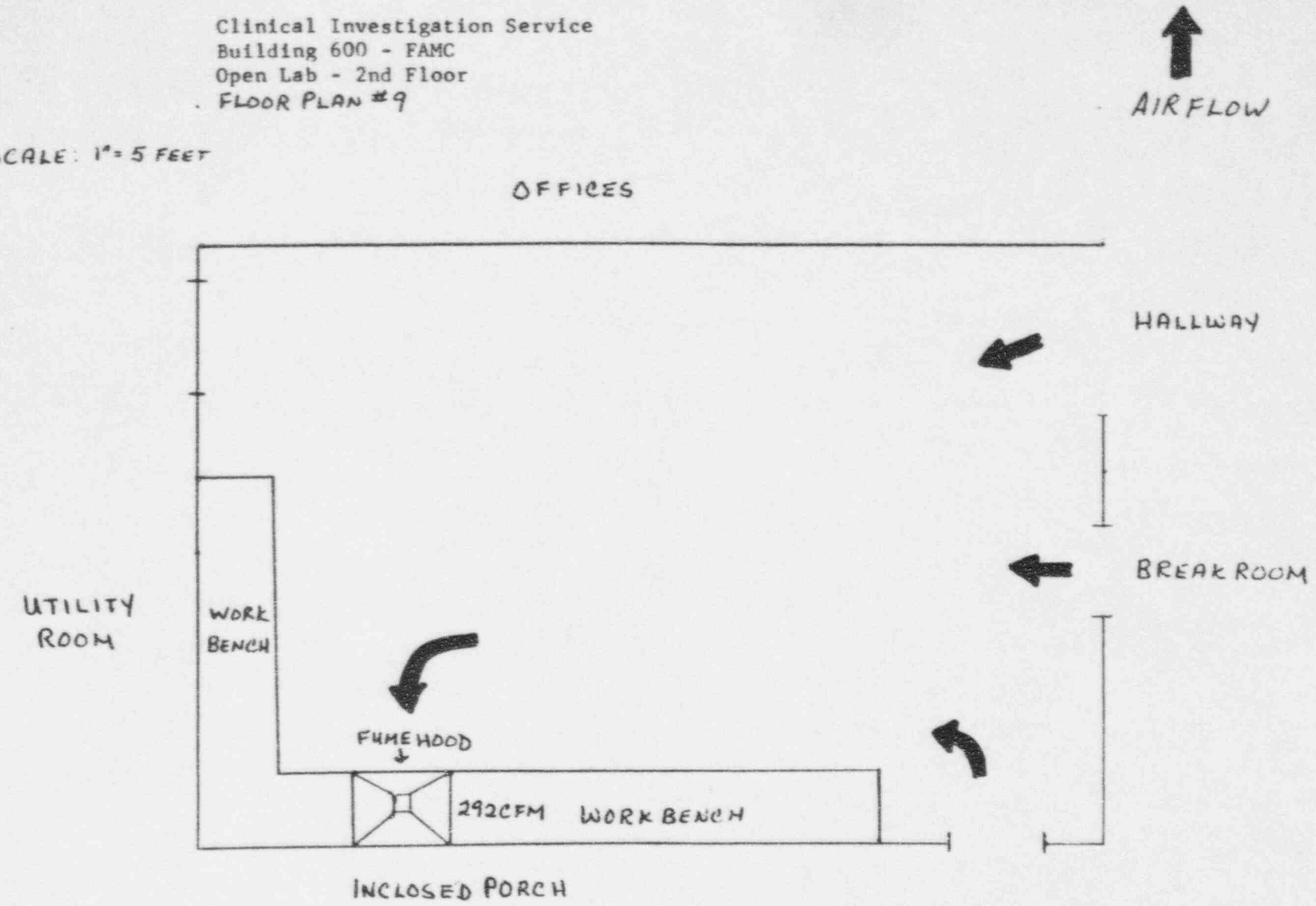
1. Location - building 600, 2nd floor.

2. Use - biochemical and RIA research.

3. Fume Hood and Air Flow - as indicated.

Clinical Investigation Service
Building 600 - FAMC
Open Lab - 2nd Floor
FLOOR PLAN #9

SCALE: 1" = 5 FEET



ROOMS 211 & 215 - CLINICAL INVESTIGATION SERVICE

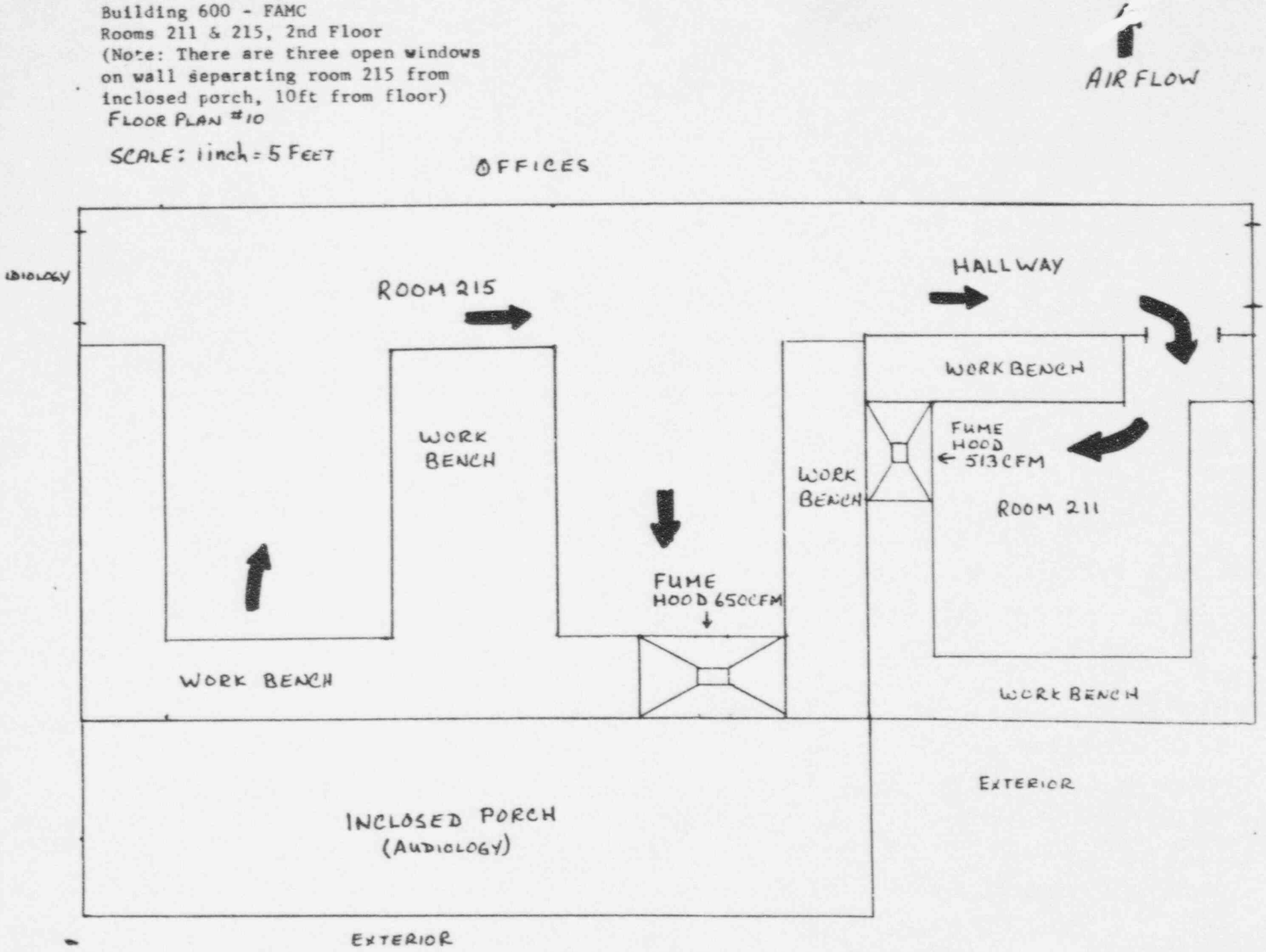
1. Location - building 600, 2nd floor.

2. Use - RIA Research.

3. Fume Hood and Air Flow - as indicated.

Clinical Investigation Service
Building 600 - FAMC
Rooms 211 & 215, 2nd Floor
(Note: There are three open windows on wall separating room 215 from inclosed porch, 10ft from floor)
FLOOR PLAN #10

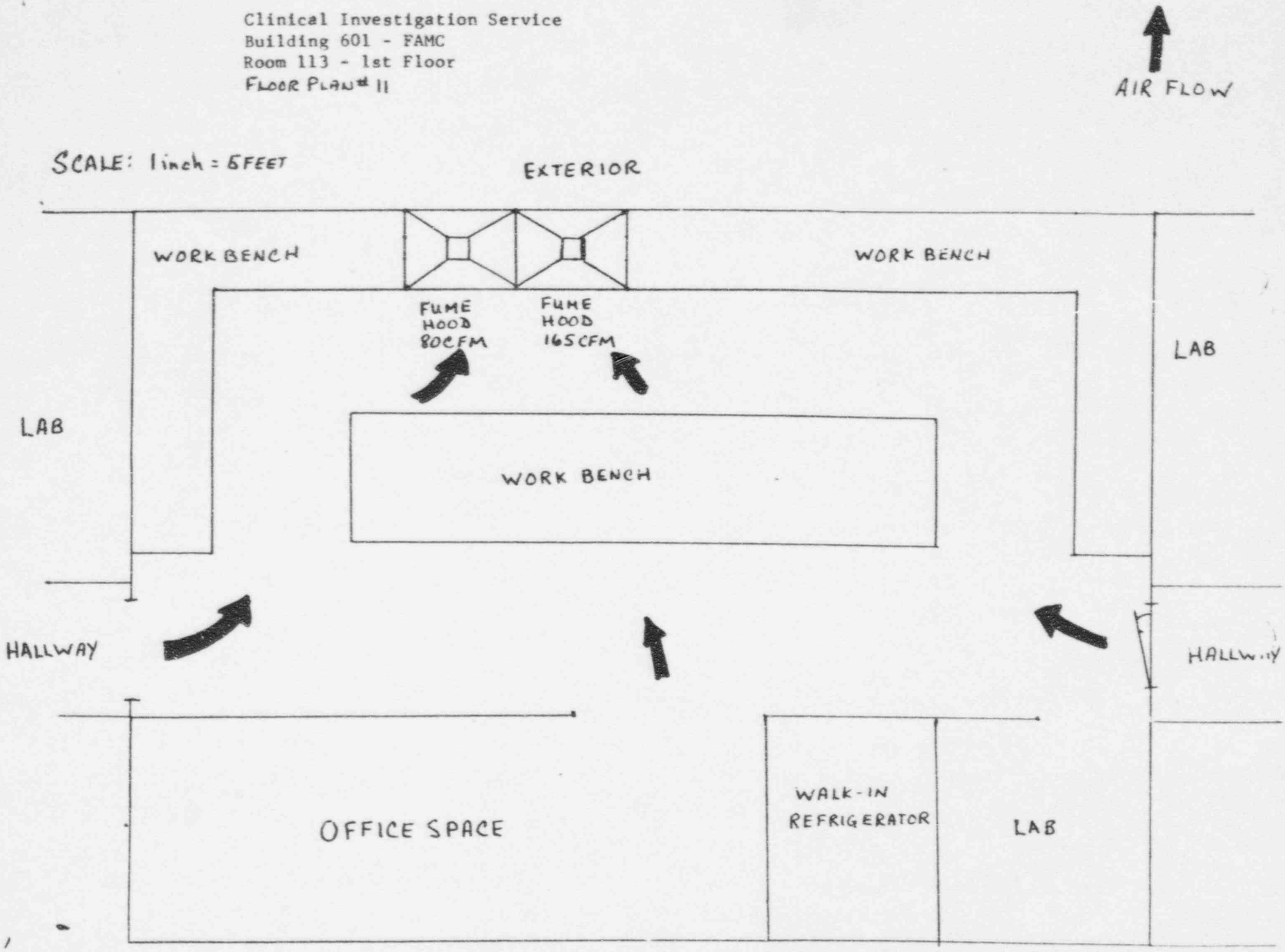
SCALE: 1inch = 5 FEET



ROOM 113 - CLINICAL INVESTIGATION SERVICE

1. Location - building 601, 1st floor.
2. Use - RIA Research (H-3, C-14) and liquid scintillation preparation.
3. Fume Hood and Air Flow - as indicated.

Clinical Investigation Service
Building 601 - FAMC
Room 113 - 1st Floor
FLOOR PLAN # 11



ROOM 216 - CLINICAL INVESTIGATION SERVICE

1. Location - building 601, 2nd floor.

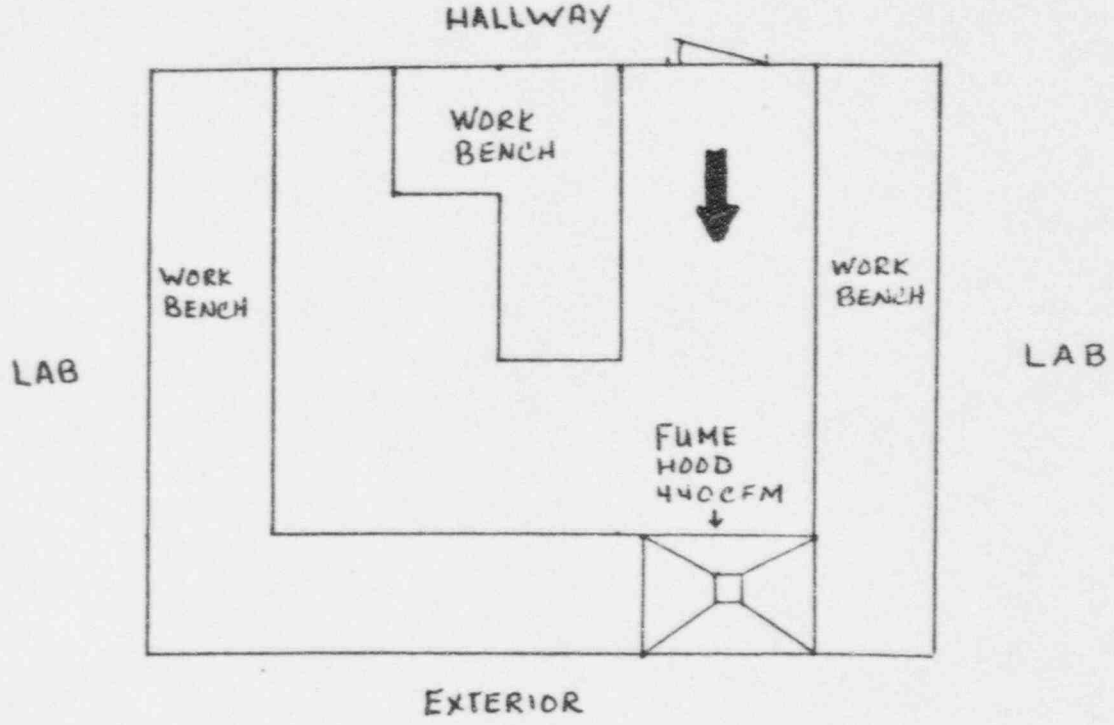
2. Use - physiological and animal research.

3. Fume Hood and Air Flow - as indicated.

Clinical Investigation Service
Building 601 - FAMC
Room 216 - 2nd Floor
FLOOR PLAN #12

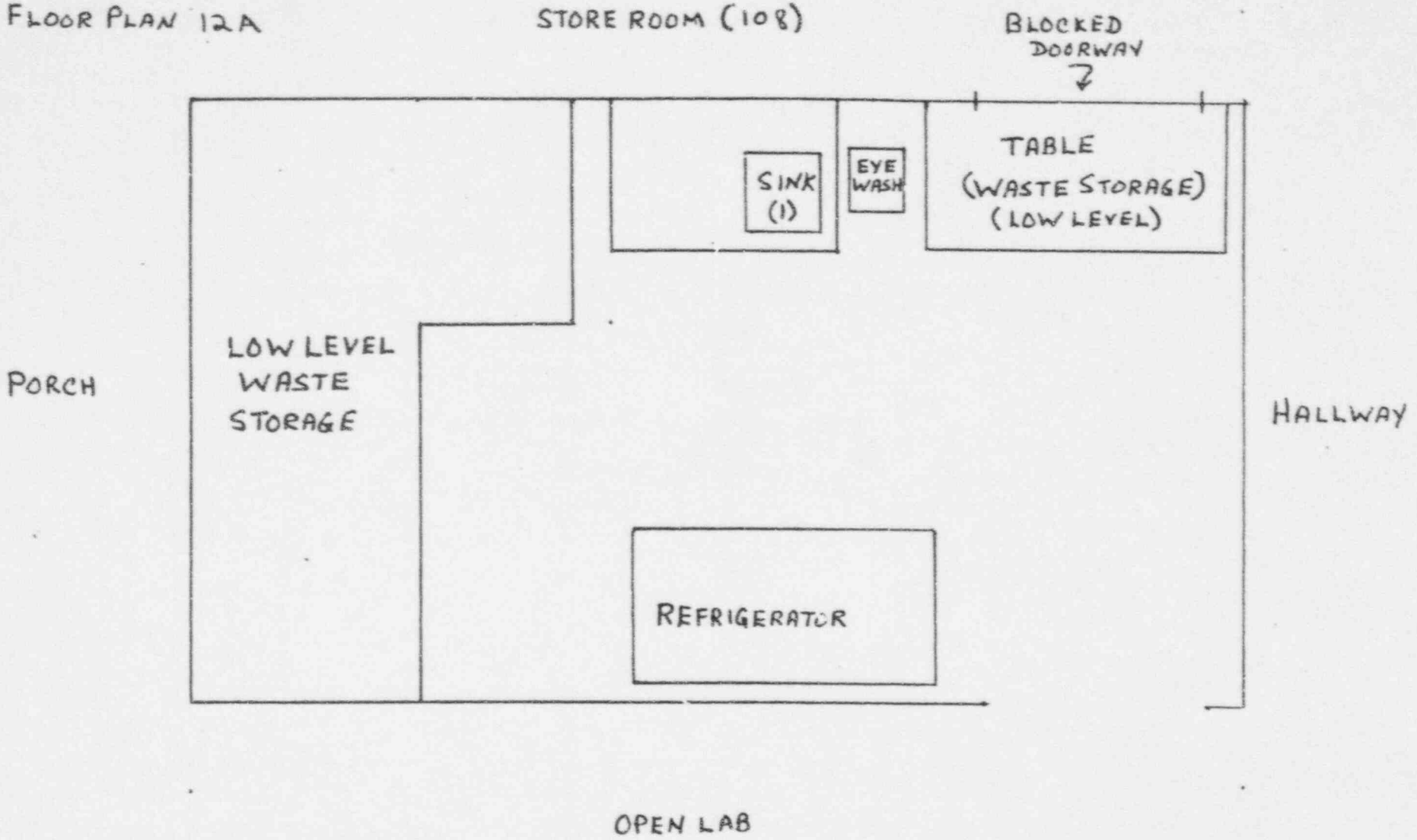
AIRFLOW

SCALE: 1 inch = 5 FEET

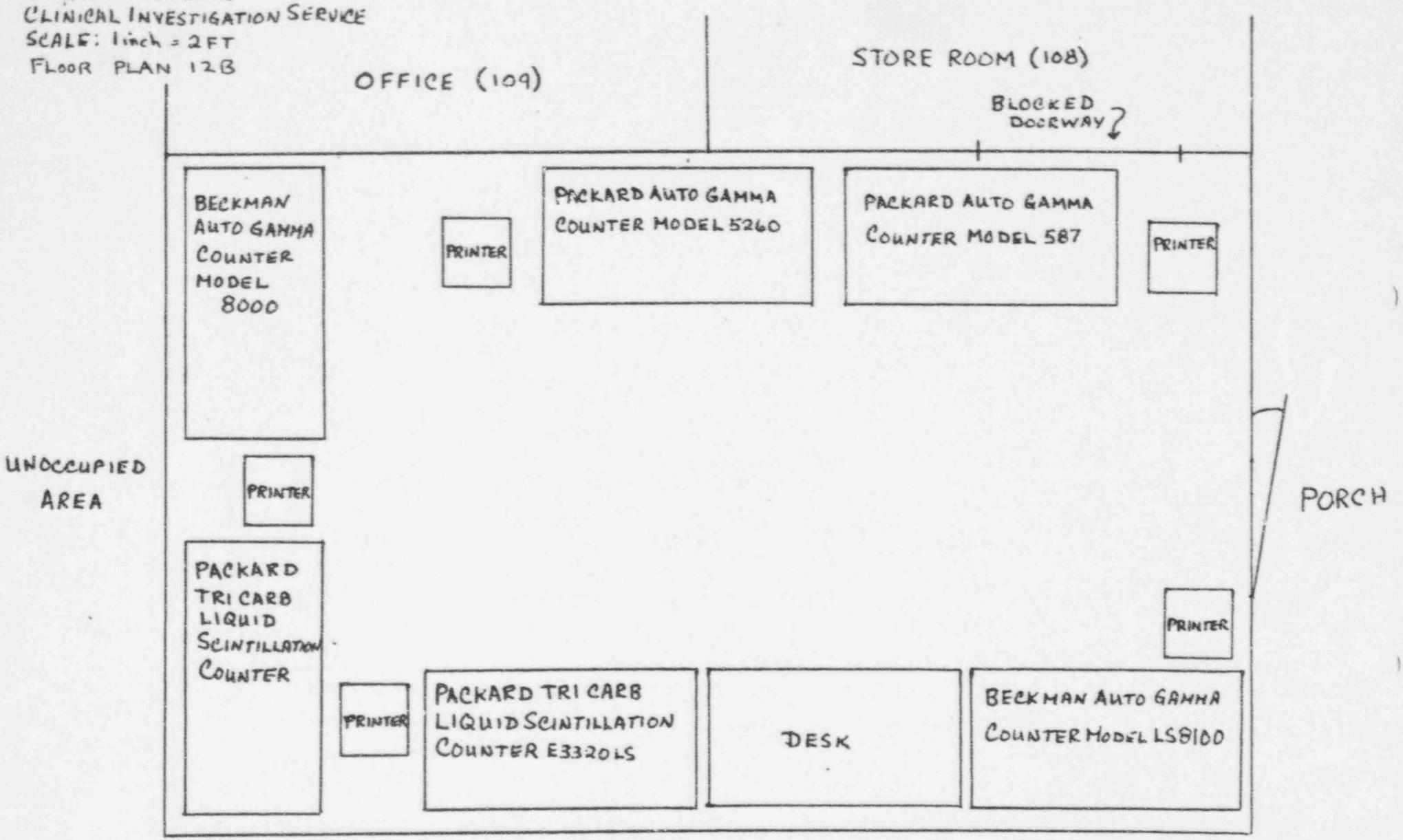


WASTE LAB - ROOM 107
BLDG 600 1ST FLOOR
CLINICAL INVESTIGATION SERVICE
SCALE: 1 inch = 2 FT
NOTE (1): SINK IS NOT
USED FOR RADIOACTIVE WASTE

FLOOR PLAN 12A

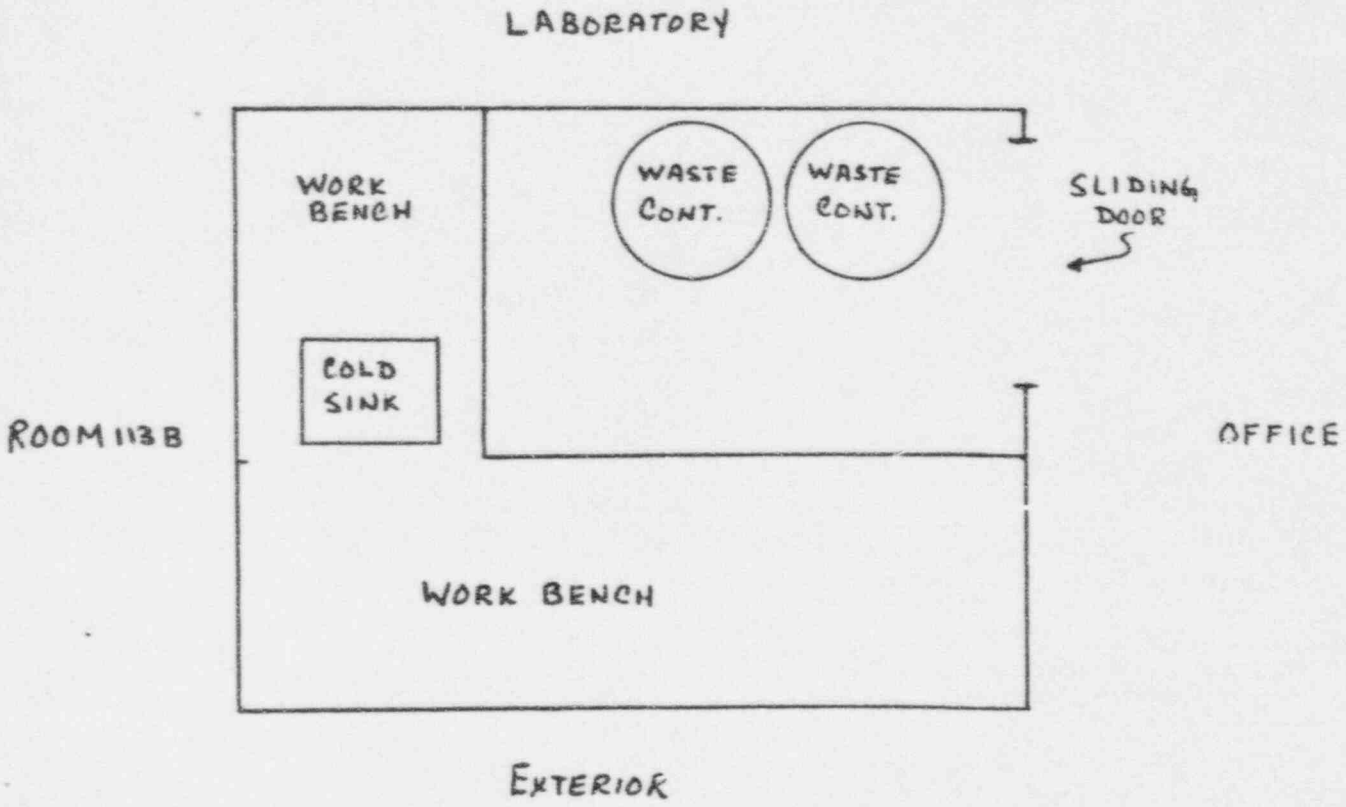


COUNTING LAB - ROOM 111
BLDG 600 1ST FLOOR
CLINICAL INVESTIGATION SERVICE
SCALE: 1 inch = 2 FT
FLOOR PLAN 12B

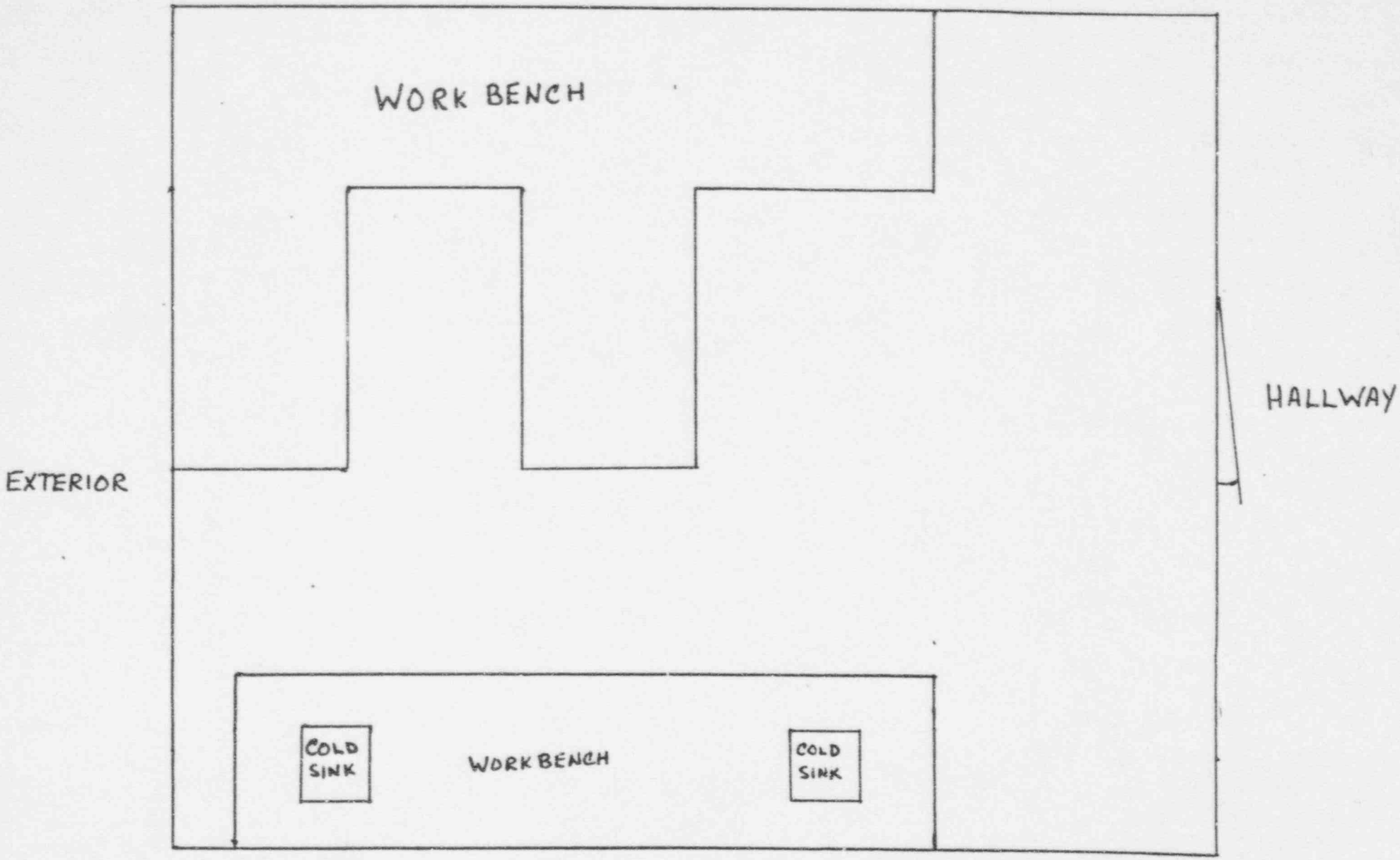


12B

TRITIUM LAB - ROOM 113C
BLDG 601 - CLINICAL INVESTIGATION SERVICE
SCALE: 1 inch = 2 FT
FLOOR PLAN 12C

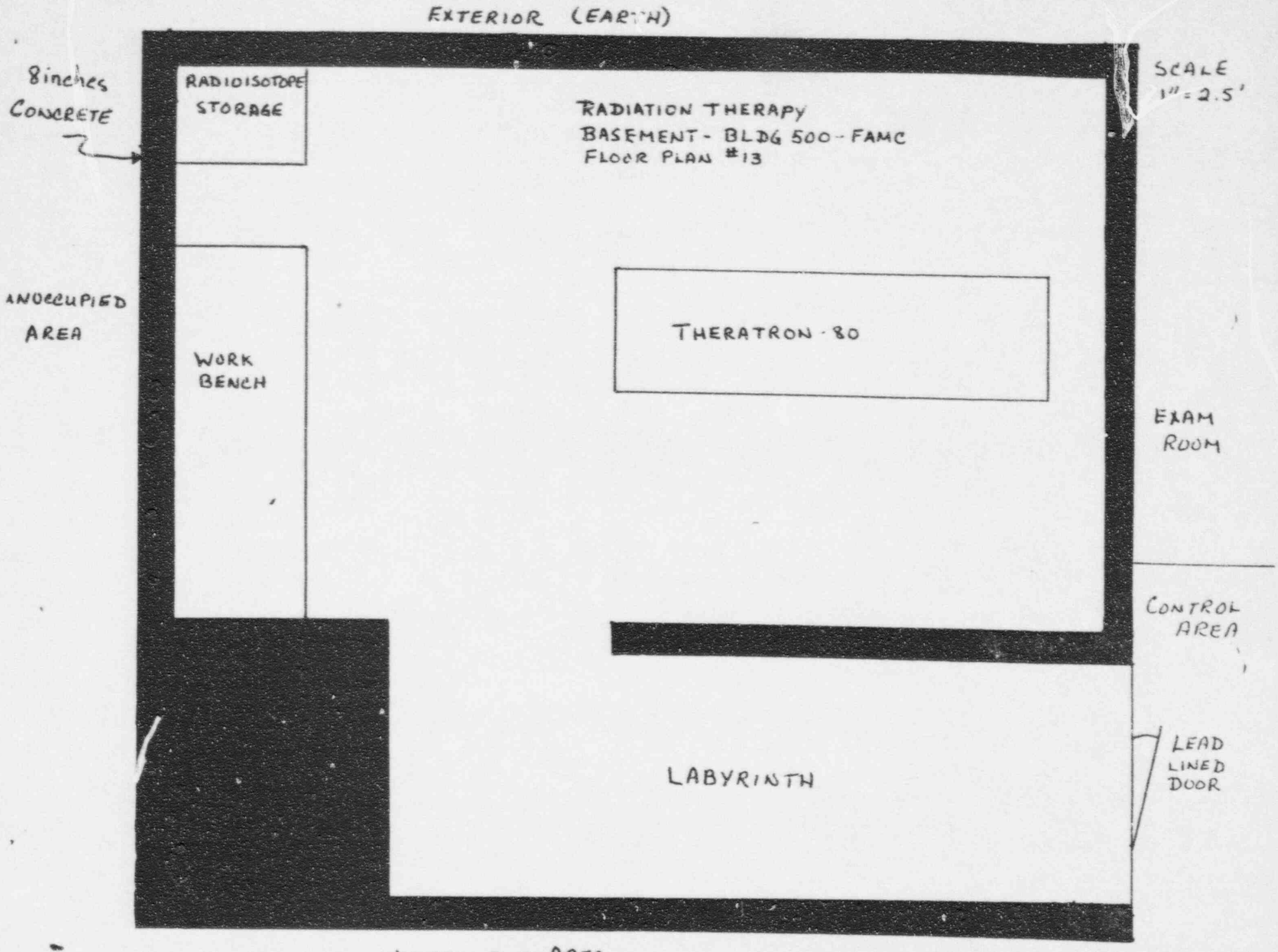


CHROMIUM-51 LAB - ROOM 113B
BLDG 601 - CLINICAL INVESTIGATION SERVICE
SCALE: 1 inch = 2 FT
FLOOR PLAN 12D



RADIATION THERAPY

1. Location - basement, building 500.
2. Use - cobalt therapy; and Cs-137, I-125, Ir-192 therapy source storage.
3. Facilities
   a. Cobalt theratron 80 unit.
   b. Isotope storage safe.
4. Shielding - as indicated.


EXTERIOR (EARTH)
8 inches CONCRETE
RADIOISOTOPE STORAGE
RADIATION THERAPY
BASEMENT - BLDG 500 - FAMC
FLOOR PLAN #13
SCALE 1" = 2.5'
UNOCCUPIED AREA
WORK BENCH
THERATRON - 80
EXAM ROOM
CONTROL AREA
LABYRINTH
LEAD LINED DOOR
UNOCCUPIED AREA

RIA LAB - DEPARTMENT OF PATHOLOGY

1. Location - building 500, 2nd floor.

2. Use - RIA procedures

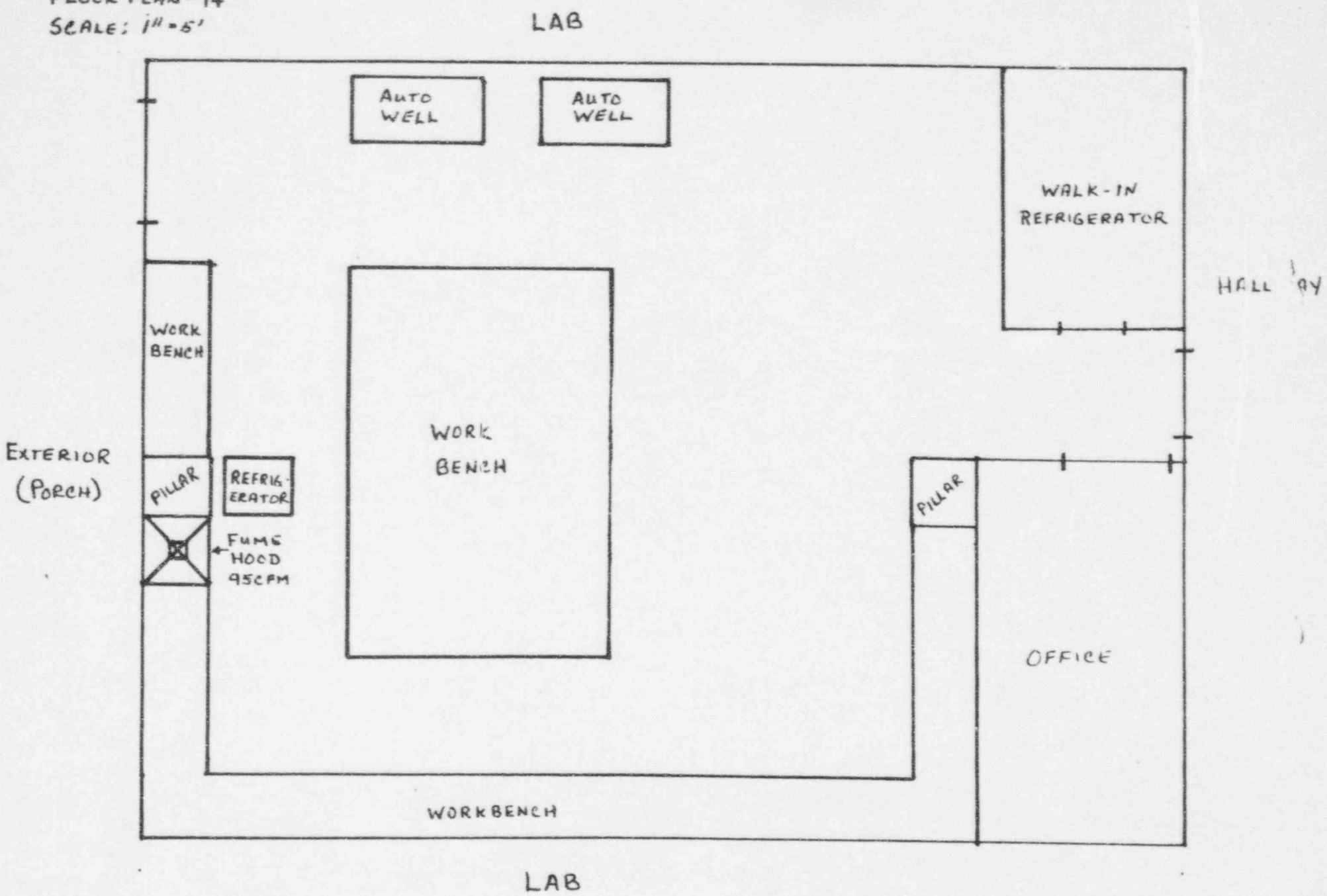
3. Equipment

a. Packard Instrument Automatic Well Counter Model 5360 - 600 Sample Capacity.

b. Packard Instrument Automatic Well Counter Model 5320 - 600 Sample Capacity.

c. Fume Hood and Air Flow data is not applicable, as the fume hood is not used for radioactive materials. Only exempt quantity RIA kits are used in this lab.

RIA LAB - DEPARTMENT OF PATHOLOGY
BUILDING 500 - 2ND FLOOR - ROOM 2109
FLOOR PLAN #14
SCALE: 1" = 5'



ITEM 12

Personnel Training Program

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

12. Personnel Training Program

The Personnel Training Program is administered by the RPO and the Health Physics Section.

The following appendix of BAMC Reg 40-604, Radiation Safety, describes the basic program, which is designed to assure compliance with 10CFR19.12.

The mode of instruction is lecture/demonstration and/or videotape presentation. Preassignment and annual refresher training each comprise at least one hour of classroom instruction. Special (change of working conditions etc) classes will have whatever duration is required to effectively present the material, in the judgement of the RPO.

ITEM 12

Appendix H of FAMC Reg 40-604
Personnel Training Program

APPENDIX H

PERSONNEL TRAINING PROGRAM

1. Purpose. The purpose of this appendix is to establish the standards of training for all personnel who work with radioisotopes and x-rays at Fitzsimons Army Medical Center (FAMC).

2. General. The standards of training for occupationally exposed personnel ("radiation workers") and support personnel who might be exposed at FAMC have been established by the Radioisotope Committee. The training outlined below, or its equivalent, is considered prerequisite for individuals who work in categories described. These requirements supplement those outlined in Appendix A, AR 40-37.

3. Training and experience required of individuals.

a. Radiation Therapy Service.

(1) Physicians - Approval to use the teletherapy sources and the brachytherapy sources requires that the physician be certified by the American Board of Radiology in General Radiology or Therapeutic Radiology.

(2) Technicians - It is required that therapy technicians be registered or eligible for registry examination. The degree of direct supervision by the using physician is determined by the level of training the technician has achieved.

(3) Training - Added training in health and safety are provided as necessary during routine conferences, chart rounds, and class periods in the Radiation Therapy Service.

b. Nuclear Medicine Service.

(1) Physicians - Approval to use radioisotopes in the Nuclear Medicine Service depends on proof of the physicians having achieved Board Certification or Board eligibility in either general radiology, nuclear medicine or internal medicine accompanied by documentation of his/her immediate training and experience in diagnostic and therapeutic nuclear medicine.

(2) Technicians - Technicians use and handle radioisotopes under the direction of the physician. It is required that civilian technicians be registered and that military technicians be registry eligible. Student technicians, are assigned to the service to complete the practical portion of their training and are required to have completed the total didactic course of instructions at a recognized training facility.

(3) Training - Training in health and safety is a continuing function in the Nuclear Medicine Service. Routinely scheduled lectures, conferences and demonstrations are conducted by the Chief, Nuclear Medicine Service, the senior nuclear medicine technician, the radiological physicist, and manufacturer's representatives.

c. Research and in-vitro laboratory services.

(1) Research scientists. It is required that documentation of training and experience with radioactive material be submitted with a researchers request for approval. Should researchers desiring to use isotopes and not have prior training, a series of laboratory and lecture periods are provided by the Radiation Protection Officer using the facilities and personnel of the Nuclear Medicine Service. Such training continues until the trainees demonstrate ability to safely acquire, store, handle and use the materials in question. Arrangements to attend trcining conferences at other medical institutions or at commercial vendor's facilities are made as required.

(2) In-vitro testing. In-vitro testing is accomplished by medical technologist. Documentation of the training and experience in handling radioisotopes is required prior to approval for use. Continued training in health and safety is provided during regular scheduled visits to the laboratory by the Radiation Protection Officer. When new in-vitro procedures are introduced into the laboratory, training is accomplished in these through vendor conferences and demonstrations.

d. Diagnostic Radiology Service.

(1) Physicians - Physicians do not routinely operate diagnostic x-ray units. They rely on the technicians. Fluoroscopy, by contrast is routinely operated by physicians. It is required that physicians who desire to operate any x-ray machine be familiar with the contents of TB MED 62, received training in the operation of the machine by the chief technician.

(2) Technicians - Civilian technicians are required to be registered or to be eligible for registry examination. Military technicians are required to be registry eligible. Student technicians work under direct supervision and are required to have completed the X-ray Technicians Course of Instruction (91P20) at the Academy of Health Sciences, Ft Sam Houston, Texas.

(3) Training - Routine health and safety training of physicians and technicians is accomplished on a regular scheduled basis using lectures, demonstrations and practical exercises.

e. All potentially exposed support personnel and radiation workers, to include ward personnel, janitorial personnel, fire fighters and military police, will receive sufficient training to insure they do not commit unsafe acts or violate the applicable regulations and license provisions. The

Radiation Protection Officer will provide a program of training to include at least the following topics:

(1) Areas within FAMC where radioactive materials are used or stored.

(2) Recognition of radiation symbols and warnings signs.

(3) Potential hazards associated with the radioactive materials used at FAMC.

(4) Radiological safety procedures appropriate to their respective duties.

(5) Pertinent NRC, DA and FAMC regulations.

(6) The pertinent terms of NRC licenses and DA authorizations.

(7) Their obligation to report unsafe conditions.

(8) Appropriate responses to emergencies or unsafe conditions.

(9) Their right to be informed of their personnel monitoring and bioassay results.

Personnel will be trained as above before assuming duties in which they might encounter radioactivity as well as during annual refresher training. If there is a change in duties, regulations, terms of the NRC license or other significant circumstances of the use of radioactive materials, the individual's training will be updated in keeping with the above regimen.

4. Qualification and certification.

a. Personnel may become qualified in the use of radioisotopes through the receipt of training at FAMC or through credit granted by the Radioisotope Committee for previous training and experience in the use of, handling, storage, disposal, and control of radioactive material.

b. Certification of satisfactory completion of appropriate training which is conducted under the auspices of the RPO will be provided by the organization's RPO.

c. In the case of physicians, evidence of satisfactory completion of the clinical practical experience will be provided to the RPO by the principal user under whom the experience is obtained.

d. Records of training and experience of radioisotope workers will be maintained by the RPO.

5. References.

a. Appendix A, USNRC Licensing Guides - Medical Programs.

b. TR 31 - Training in Radiological Protection: Cirricula and Programming, International Atomic Energy Agency, Vienna, 1964.

c. 10 CFT 30 - Rules of General Applicability to Licensing of Byproduct Material, Rules and Regulations of the US Atomic Energy Commission.

d. TB MED 62 - Diagnostic X-ray Protection.

e. NBS Handbook Number 93.

f. NCRP Reports Numbered: 8, 22, 28, 30, 33, 34, 35, 36, and 40.

g. ICRU Reports Numbered: 10c, 10d, and 10e.

ITEM 13

Procedures for Ordering and Receiving Radioactive Material:
Appendix I of FAMC Reg 40-604
Receipt, Transfer and Shipment of Radioactive Material

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

APPENDIX I

RECEIPT, TRANSFER AND SHIPMENT OF RADIOACTIVE MATERIAL

1. Purpose. The purpose of this appendix is to familiarize principal users and other personnel with the health physics aspects of radioactive material procurement, receipt, transfer, and shipment.

2. General.

a. The Radiation Protection Officer, in coordination with the FAMC Transportation Officer, controls the movement of all radioactive material onto, off of, and within the installation.

b. The Radiation Protection Officer, in coordination with the Directorate of Industrial Operations controls the procurement, receipt, and transfer of all radioactive material at FAMC.

c. Questions concerning procurement, receipt, transfer, and shipment should be directed to Radiation Protection Officer, extension 3826/3916.

3. Procurement of radioactive material.

a. General.

(1) A principal user may only request procurement of those radioisotopes currently authorized for his use by the FAMC Radioisotope Committee, subject to the limitations of his authorization.

(2) The maximum quantity which may be ordered at any one time is limited by the maximum activity of that radioisotope which the user is authorized to possess unless arrangements have been made with the Radiation Protection Officer.

(3) Receipt and/or transfer of gifts containing radioactive material shall not be accomplished without prior approval of the Radiation Protection Officer. This has particular application in those instances where normal supply channels are not utilized. Delivery of all gifts will be coordinated with the Radiation Protection Officer.

b. Principal user.

(1) The principal user shall submit a completed DA Form 3953 (Purchase Request and Commitment) from his department, service or organization, through the Radiation Protection Officer to Materiel Division for the procurement of all radioactive materials.

(2) In addition to the information required by AR 37-108, each DA Form 3953 shall contain the following:

(a) Radionuclide, chemical form, and total activity (activity is given as microcurie (uCi), millicurie (mCi), curie (Ci), microgram (ug), milligram (mg), gram(g), or milligram-radium equivalent (mg Ra eq), as appropriate).

(b) Date required or delivery date.

(c) With regard to the procurement or disposal of radioactive commodities, the principal user and/or Materiel Division will coordinate with the Radiation Protection Officer prior to the submission of DA Form 2765 or 2765-1 (Request for Issue or Turn in).

(d) Instructions to the vendor to ship to the address shown in paragraph 3c(3).

c. Purchasing.

(1) Prior to placing any orders for radioactive material, purchasing personnel will examine the Purchase Request to insure that the Radiation Protection Officer or his authorized representative has indicated approval.

(2) In order to obtain approval, the Radiation Protection Officer must be furnished with the following information from the DA Form 3953.

(a) Identity of the radioisotope(s) being requested.

(b) Total activity of the radioisotope desired.

(c) Delivery date of the requested radioactive material.

(3) After approval has been granted, the authorized purchasing personnel will place the order and request delivery by the required date, with instructions for the vendor to ship to the following address (unless specifically exempted as authorized by the Radiation Protection Officer):

(a) For any item destined for any organization located at FAMC:

Radiation Protection Officer
Building 500
Radiation Therapy Service
Fitzsimons Army Medical Center
Denver, Colorado 80240

(b) Any item requiring special handling or pick up by the Radiation Protection Officer, must be coordinated with the Radiation Protection Officer as soon as the requirement is identified.

4. Receipt of radioactive material.

a. All incoming shipments of radioactive material will be received by the Radiation Protection Officer or Nuclear Medicine Service, FAMC. The following procedure will then be followed:

(1) The shipping container and packing material will be inspected for damage and monitored for contamination. The package will be treated as contaminated until proven otherwise.

(2) The labeling of the package, the packing slip, and other documents will be compared with the DA Form 3953 or DA Form 2765 to insure the accuracy of the shipment. All documents will be sent to Storage Section, Materiel Division, Building 211, for preparation of receiving reports.

(3) Procedures for package inspection are outlined in Section I to Appendix I.

(4) The user is then notified to pick up.

(5) Appropriate entries are made in the Radioactive Material Receipt Files and Inventory Records.

b. If shipments are found to be contaminated, they will be decontaminated to acceptable levels by the Radiation Protection Officer prior to delivery to the user.

c. Under no circumstances will an incoming shipment of radioactive material be refused when delivered.

d. The user should note the exposure rate measurements posted by the Radiation Protection Officer and govern his handling and storage of the radioactive material accordingly.

e. The Radiation Protection Officer's inspection does not constitute an assay or an evaluation of the pharmaceutical quality of the radionuclide.

f. The Radiation Protection Officer operates during normal FAMC duty hours. After duty hours, radioactive material is to be received only by the Administrative Officer of the Day (AOD) who will place the shipment in the custody of the x-ray technician on duty in the Department of Radiology.

g. The principal user must notify the Radiation Protection Officer if an urgent or specially refrigerated shipment is expected. The Radiation Protection Officer

will insure the prompt inspection and survey of the shipment so that the delivery will not be unduly delayed.

5. Transfer of radioactive material.

a. Transfer of radioactive material within FAMC shall be accomplished only between persons authorized to use those radioisotopes by the FAMC Radioisotope Committee.

b. Transfer of radioactive material between principal users at FAMC and other activities or agencies outside the jurisdiction of FAMC shall be coordinated with the Radiation Protection Officer. The principal user, in coordination with the Radiation Protection Officer, will prepare a DA Form 2791-R (Radioactive Material Movement) for the transport of radioactive material. The Radiation Protection Officer must have proof in writing that the recipient is licensed or authorized to possess the radioactive material, by the USNRC or other authority, before the transfer is accomplished.

c. Transfer of all adapted or experimental items of equipment containing radioactive material that are to be returned to a vendor for repair, return or replacement, and/or disposal shall be processed in the following manner:

(1) The item containing the radioactive material shall not be removed from its normal location without the approval of the Radiation Protection Officer.

(2) The principal user shall contact the Radiation Protection Officer for instructions.

(3) The principal user shall prepare a DA Form 2496 (Disposition Form) addressed to the Radiation Protection Officer, FAMC, which shall contain the following information:

(a) A statement requesting that the equipment be returned to the appropriate vendor for repair and return, or returned to the vendor for replacement and/or disposal.

(b) Complete address of the vendor.

(c) Make and model number of the equipment.

(d) Serial number of the equipment and/or the radioactive source.

(e) The radionuclide present.

(f) The total activity of the source (uCi, mCi, ug, mg, g, or mg Ra eg, as appropriate).

(4) The principal user shall coordinate with his organization supply personnel in the preparation of a DA Form 2407 (Maintenance Request - MR) to be submitted to the Maintenance Division, FAMC. It is imperative that the MR contain the make, model, serial number, Federal Stock Number (FSN) of the item, radioisotope, total activity, and description of the work to be performed.

(5) It is the responsibility of the Maintenance Division, FAMC; Purchasing and Contracting (P&C) Division, FAMC, to coordinate with the Materiel Division in completing the necessary documents for shipment of equipment. These documents are:

(a) Shipping Document. DD Form 1348-1 or DD Form 1149-4 with fund citation and Purchase Order number.

(b) DD Form 1155. Order for Supplies and Services.

(6) The Maintenance Division shall notify the Radiation Protection Officer to coordinate the pick up of the shipping documents from the Maintenance Division and the equipment from the principal user.

(7) All adapted or experimental equipment containing radioactive material being returned to FAMC by the vendor shall be shipped to the address given in paragraph 4c(3)(a).

6. Shipment of radioactive material.

a. The Radiation Protection Officer will process all outgoing shipments identified as containing radioactive material and returnable containers for radioactive material departing FAMC.

b. The principal user shall coordinate with DIO and Materiel Division in the preparation of the Shipping Document.

c. The Radiation Protection Officer or his representative will insure that the container is properly identified, described, packaged, and labeled in accordance with existing regulations and that the shipping documents and instructions are properly forwarded.

7. References.

a. Title 10, Code of Federal Regulations, Rules and Regulations of the US Atomic Energy Commission.

b. Title 42, Code of Federal Regulations, Rules and Regulations of the US Public Health Service, Department of Health, Education and Welfare.

c. Title 49, Code of Federal Regulations, Rules and Regulations of the Department of Transportation.

d. AR 37-108, General Accounting and Reporting for Finance and Accounting Offices.

e. AR 710-2, Materiel Management for Using Units, Support Units and Installations.

f. TM 38-750, The Army Maintenance Management Systems.

ITEM 14

Procedures for Safely Opening Packages Containing Radioactive Materials:
Appendix I of FAMC Reg 40-604, Section I

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

SECTION I
INSTRUCTIONS FOR SAFELY OPENING PACKAGES TO COMPLY WITH SECTION 20.205, 10 CFR 20

Certain packages require monitoring of radiation levels and of external surfaces for contamination within a specified time after receipt (see 10 CFR 20.205(b) & (c)). Note that practically everything received by a hospital with few exceptions (example: liquid tritiated compounds greater than 10 mCi) is exempted from this; however, 20.205(d) requires that procedures be established for "safely opening packages" of all licensed material with no exceptions.

a. General set-up.

(1) Packages should be delivered to one specific location in the institution, e.g., Radiation Safety Office, where personnel are knowledgeable in safe handling. Establish a specific location within the lab for receipt and inspection. Treat as contaminated until proven otherwise, especially if damaged. Place package on surface with absorbent material during survey.

(2) Arrange to open and inspect packages as soon as possible after receipt. Items B-4 and 5 will alert personnel to the intensity of the radiation field in which they are working; B-6 and 8 will warn of any contamination.

(3) Plan to make a record of results and pass on to final user to alert him to condition of the shipment. This record is also useful in communication with the vendor in case of problems.

(4) Plastic or other protective gloves and lab coats should be worn for opening packages for the protection of the surveyor.

(5) If the manufacturer's directions for opening or unpacking radicactive material are provided, follow these directions in addition to those below.

(6) Packages containing radioactive materials with associated high exposure levels may require some or all of the following steps to be performed behind a radiation shield and/or using other appropriate safety measures.

b. Procedure for packages inspection (see NOTE #1).

(1) Receive in prepared, protected place.

(2) Observe for mechanical damage - record condition.

(3) Determine if exempt from required inspection - record.

(a) If exempt - continue when practical (not required by NRC).

(b) If no exempt - continue within.

1 3 hours if received during normal work hours.

2 12 hours if received after normal work hours.

(4) Measure exposure rate[1] at 3 feet from package surface - record.

(a) If ≥10 mR/hr - proceed with caution - expedite notification.[2]

(5) Measure surface exposure rate and record.

If ≥200 mR/hr - proceed with caution - expedite notification.[2]

---

[1] Use thin window detector (if the outside is contaminated, it will detect beta particles that could be an external radiation hazard).

[2] Notify immediately:

a. Radiation Protection Officer.

b. The public carrier that delivered the package.

c. The NRC Regional Office of Inspection and Enforcement (by phone and telegraph).

(6) Observe outer package for leakage stains - record condition.

(a) If stains present - wipe 100 Cm^2 area with dry wipe and assay[3] - record.

(b) If wipe has 0.01 uCi (22,000 DPM) - proceed with caution. Expedite notification.[2]

(7) Open the outer package and remove packing slip. Open inner package to verify contents (compare requisition packing slips, label on bottle) and integrity of final source container (inspect for breakage of seals or vials, loss of liquid, discoloration of packing material). Check also that shipment does not exceed possession limits.

(8) Wipe external surface of final source container with moistened cotton swab or filter paper held with forceps, assay[3] and record.

(9) Monitor[3] the packing material and packages for contamination before discarding:

(a) If contaminated, treat as radioactive waste.

(b) If not, obliterate radiation labels before discarding in regular trash.

NOTE #1 - In institutions with separate Radiation Protection Offices (RPO) and user laboratories, the RPO may only do external measurements on the package (i.e., B-1 through B-6). The remainder of the procedures may be performed by the user laboratory.

NOTE #3 - An end window GM or gas flow proportional counter with window thickness $\geq$1.5 mg/cm^2 normally may be used for assaying beta emitters at or above C-14 energies; low energy beta emitters will require liquid scintillation counting. A gamma-scintillation counter should be used for pure gamma emitters.

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

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_____DPM
(eff-( ))

7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS_____
mR/hr, CPM above Pkg.

8. IF PACKAGE WAS SHIPPED WITH DRY ICE, WAS DRY ICE PRESENT IN PACKAGE AT TIME OF RECEIPT?_____YES_____NO_____
NA_____.

9. DISPOSITION OF PACKAGE AFTER INSPECTION:_____

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

Figure 1-1. Radioactive Shipment Receipt Report.

ITEM 15

General Rules for the Safe Use of Radioactive Material

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

15. General Rules for the Safe Use of Radioactive Material

a. Procedures for obtaining permission to use radioactive material from the Radioisotope Committee are outlined in Appendix A of FAMC Reg 40-604, Radiation Safety, Tab A.

b. The use of laboratory apparel and equipment is prescribed in Appendix B of FAMC Reg 40-604, Section I, Tab B.

c. The use of fume hoods or glove boxes is prescribed by the RPO and Radioisotope Committee as part of the control of procedures, based on the methods of the given procedure. Consideration is given to those factors which effect ambient air concentrations (isotope, chemical/physical form, process being performed, etc.) in order to comply with 10CFR, 20.103 and 20.106.

Current areas of concern are reflected in the enclosed SOP's: Iodination Procedures; Preparation of Therapeutic Iodine Doses and Opening of Sealed Containers (Nuclear Medicine Service), Tab C.

Other concerns for non-airborne contamination during handling of liquid or loose radioactive materials are reflected in (1) the Lab Rules cited in b. above, (2) approvals for procedures by the Radioisotope Committee.

d. Preparation of radiopharmaceuticals, generator elution and related procedures in Nuclear Medicine are performed behind the shields in the Isotope Lab (drawings and details listed with item 11, Facilities and Equipment).

Syringe shields are used in the preparation and administration of patient doses.

Aditional shielding requirements may be imposed by the RPO and/or Radioisotope Committee for any proposed use of radioactive material, to include animal and in vitro procedures.

e. An SOP for the Preparation and Assay of Patient Doses (Nuclear Medicine Service) is enclosed, Tab D.

f. An SOP for the movement of material between rooms and in hallways and corridors is enclosed, Tab E.

g. Requirements for storage of materials and labelling/posting of containers/areas are outlined in Appendix D of FAMC Reg 40-604, enclosed, Tab F.

As implied by the use of the term "restricted area" in Appendix D of FAMC Reg 40-604, the acess to any area where radioactive materials are stored is controlled by physical security (locked or barred doors) and/or administrative control by the principal user.

Storage areas used for large amounts of byproduct materials will be shielded and controlled so as to keep exposures ALARA. There is currently one such significant storage area:

(1) Nuclear Medicine Service isotope Lab-generator prep area, storage area, fume hood - these areas are used to store Tc-99 generators, I-131 doses, Xe-133 vials and other isotopes for diagnostic doses. Shielding is provided by 2 inch interlocking lead brick.

h. All occupationally exposed personnel are put on the FAMC film badge program. This program uses Army film badges and is centrally managed by the Health Physics Section, Bldg 514, in accordance with Army Regulation 40-14. Photodosimetry Reports (DA Form 1141) are maintained by Health Physics. Film badges are collected and exchanged on a monthly basis by Health Physics.

i. Waste disposal procedures are promulgated as part of FAMC Reg 40-604 (Appendix L, enclosed), Tab G. All waste disposal is centrally managed by the RPO.

j. Contamination control procedures are set forth in the Laboratory Rules, Section I of Appendix B, FAMC Reg 40-604, enclosed, Tab B.

ITEM 15

Appendix A of FAMC Reg 40-604
Authorization to Use Radioactive Materials

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

APPENDIX A

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

1. Purpose. The purpose of this Appendix is to describe the administrative policies and procedures relating to the use of radioactive material.

2. General. FAMC has been issued various NRC Licenses and DA Authorizations to permit the receipt, possession, storage, use, transfer, and disposal of radioactive material within the installation. No individual may be licensed by the NRC to use radioisotopes at FAMC. Accordingly, the possession and use of radioactive materials by individuals at FAMC is permitted only when specifically authorized by the FAMC Radioisotope Committee.

3. Definitions.

a. US Nuclear Regulatory Commission License. A license issued to FAMC which permits the receipt, possession, storage, utilization, transfer, and disposal of certain radioactive material at FAMC subject to specific conditions. USNRC Licenses are issued for nuclear reactor byproduct material.

b. Department of the Army Authorizations. An authorization issued by Department of the Army to FAMC which permits the receipt, possession, storage, utilization, transfer, and disposal of naturally-occurring and accelerator-produced radioactive material at FAMC.

c. FAMC Radioisotope Authorization. An authorization issued by the FAMC Radioisotope Committee to an individual, within the authority of the NRC License and DA Authorization held by FAMC, to receive, possess, store, use, transfer, and dispose of radioactive material. FAMC Radioisotope Authorizations are subject to the conditions of the NRC Licenses, the Code of Federal Regulations, Department of the Army regulations, and this FAMC regulation.

d. Human use of radioactive materials refers to the diagnostic and therapeutic application of radioactive material to a human being.

e. Non-human use of radioactive materials refers to those applications in which radioactive material is not applied or injected into human beings. In-vitro studies of human tissues are included in this category providing none of the product material is to be administered to humans.

f. Principal user is an individual who, by virtue of their training and experience with radioactive material, has been authorized by the FAMC Radioisotope Committee to possess and use radioactive material for a given purpose. A principal user bears the responsibility for the safe handling of the material and for proper precautionary

measures to protect themselves and others from unwarranted exposure to radiation. They may dictate such rules, procedures, or other restrictions as they deem necessary to effect the proper handling of the radioactive material. They are directly responsible to the FAMC Radioisotope Committee.

g. Co-worker is an individual who possesses adequate training and experience with comparable radioactive material or equipment to qualify them as a principal user. A co-worker performs such duties under the authorization of the principal users as directed. A co-worker is responsible to the principal user for safe and proper handling of radioactive materials.

h. Trainee is an individual who does not possess adequate training and experience to be authorized as a principal user themselves. They are assigned to this category so that they may obtain the necessary experience under the direct supervision of the principal user and co-workers. It is the aim of the trainee to obtain suitable training and experience to become qualified as a principal user or co-worker.

i. Technician is an individual who, under the supervision of the principal user and/or co-worker, performs certain routine duties involving the use of radioactive material. They do not possess suitable training and experience to be classified as a principal user or co-worker, and are not undergoing training as would qualify them to obtain that status. Technicians must be trained in the safe handling of radioactive material, contaminatoon control, and precautionary measures which may be taken to protect themselves and others from unwarranted exposure to radiation.

j. Health physics is a profession devoted to the protection of man and their environment from unwarranted radiation exposure.

4. Procedures for initially obtaining FAMC Radioisotope Committee authorization to use radioactive material.

a. Non-human use. The principal user will prepare in final form the following documents:

(1) Letter or Disposition Form (DA Form 2496) to the Chairperson, FAMC Radioisotope Committee, requesting authorization to use radioactive material for in-vitro research and clinical testing and/or in-vitro research and testing in lower animals. The correspondence will contain:

(a) The isotope to be used, its chemical and physical form;and the maximum quantity to be possessed by the user at one time, for the given procedure.

(b) A detailed description of the intended use of the radioactive material, sufficient to allow the Radiation Protection Officer to make all determinations regarding radiation protection for that procedure.

(c) The exact location (building and room) where the material will be used.

(d) Principal user and their major assistants.

(2) A standard curriculum vitae.

(3) A complete and accurate statement of the principal user's training and experience in the procurement, storage, use, and disposal of radioactive materials.

b. Human use - standard medical diagnostic and therapeutic procedures.

(1) Letter or Disposition Form (DA Form 2496) to the Chairperson, FAMC Radioisotope Committee, requesting authorization to use radioactive material in humans for specified standard diagnostic and therapeutic procedures. The correspondence will contain:

(a) The isotope to be used, its chemical and physical form; and the maximum quantity to be possessed by the user at one time, for the given procedure.

(b) A detailed description of the intended use of the radioactive material, sufficient to allow the Radiation Protection Officer to make all determinations regarding radiation protection for that procedure.

(c) The exact location (building and room) where the material will be used.

(d) The principal user and their major assistants.

(2) A standard curriculum vitae.

(3) A preceptor's statement -- a complete statement of the principal users training and experience in use of the particular isotope requested as well as their experience in procurement, storage, use and disposal of the radioactive material. This should be in the format of NRC Form 313a and NRC Forms or a reasonable substitute. AEC Forms are available in the office of the Radiation Protection Officer.

c. Human use - research or investigational - new - drug (IND) status. See Section 1 to Appendix A.

d. The principal user obtains administrative approval from the individual occupying the next higher command position and forwards all documents to the following: Radiation Protection Officer, Health Physics Section, Building T-514.

e. The Radiation Protection Officer will conduct an initial survey of the contemplated laboratory facility to evaluate potential occupational hazards. The procedure and qualifications of the workers will be evaluated to insure adequate training and experience in the safe handling of radioisotopes. In the case of human uses involving non-routine medical uses of radioisotopes, the request protocol, including the research will be examined to determine whether it has been submitted to and approved by the FAMC Clinical Investigational Service.

f. The Radiation Protection Officer will verify the presence of all documents, attach additional documents as needed, and insure that the procedure, the radioisotopes, and the activity requested may be allowed within the limitations of USNRC licenses and DA authorizations issued FAMC. The file is then forwarded to the FAMC Radiositope Committee for approval.

g. Following approval, the authorization will be recorded and distribution effected. If the application involves clinical research or clinical evaluation of radiopharmaceuticals, the approval and all supporting documentation will be forwarded to the Clinical Investigation Committee.

5. Amendment of FAMC radioisotope authorization to use radioactive material. If at any time the applicant desires to deviate from the procedure, the radioisotope, or the specified investigation as described on the approved authorization, he shall request an amendment to his authorization by submitting a Disposition Form (DA Form 2496) describing the proposed changes to his FAMC radioisotope authorization, through the RPO, to the FAMC Radioisotope Committee.

6. Review and renewal of authorizations. Current authorizations will be reviewed at least annually and at other times as deemed appropriate by the RPO. After review, authorizations are renewed, discontinued, or revised in accordance with current requirements.

SECTION I

NON-ROUTINE MEDICAL USES OF RADIOACTIVE MATERIAL AUTHORIZATION TO USE RADIOACTIVE MATERIAL

1. Experimental and non-routine medical uses of by-product materials include all human uses as outlined in the Appendix to AR 40-37. Such uses may be classified into one of two phases of development:

a. Clinical research applies to a new use of radioactive material in humans. Little or nothing is known about the procedure and little or nothing has been published on the subject. The basis for proceeding with the new use in humans is derived from knowledge obtained from animal studies. This phase of development includes the initial introduction into humans and initial trials on a limited number of patients.

b. Clinical evaluation applies to the planned testing of a new diagnostic or therapeutic procedure in an appropriate series of control and diseased humans. The procedure and results of clinical research will ordinarily have been reported in the literature or at meetings. If adequate information has not been published, the applicant should have spent sufficient time with those who developed the test to be thoroughly familiar with the details.

2. The clinical research phase of experimental or non-routine medical use of radioactive material is normally limited to physicians who have broad experience in the use of radioisotopes and who have appropriate facilities and equipment available to conduct research. The individual physician to be designated as the authorized user should normally have broad and varied experience in the use of radioisotopes and in clinical research investigation.

3. The clinical evaluation phase of experimental or non-routine medical use of radioactive material is normally limited to physicians under the supervision of an individual physician with broad experience in clinical evaluation and the use of radioisotopes and under the guidance of a radioisotope committee representing a number of disciplines. Adequate resources to conduct the trials shall be available.

4. A description of human subjects to be studied must accompany each type of application. These descriptions are:

a. Persons without manifest disease - number, method of selection, age range.

b. Persons with manifest disease - number, nature of pathology, method of selection, age range.

c. Pregnant and lactating women shall ordinarily be excluded from any test not involving the condition of the pregnancy or the mammary function itself. Specify whether or not such women will be tested and if so, explain why.

5. Application for experimental uses of radioactive material in humans will be reviewed by the FAMC Radioisotope Committee prior to submission to the Clinical Investigation Committee. Applications for either clinical research or clinical evaluation of radioisotopes will contain the following documents:

a. Clinical research.

(1) Application for Clinical Investigation Project (AR 40-38) (format and instructions available from Clinical Investigation Service, extension 8951).

(2) Volunteer agreement with explanation narrative. (Format and instructions available from Clinical Investigation Service, extension 8951.)

(3) A detailed research protocol.

(4) Identity of the principal investigator with a complete copy of his curriculum vitae and qualifications for use of radioisotopes.

(5) List of all co-workers assistants and technicians, with their qualifications.

(6) Location and diagram of laboratory facilities and a detailed description and inventory of radiation detection instrumentation and its intended use.

(7) Since volunteers are to be used as human subjects or research, the provisions of AR 70-25 apply and the applicant must obtain the written consent of the Secretary of the Army secured in accordance with that regulation.

b. Clinical evaluation.

(1) Application for Clinical Investigation Project (AR 40-38, FAMC Reg 40-8). (Format and instructions available from Clinical Investigation Service, extension 8951.)

(2) Volunteer agreement with explanatory narrative. (Format and instructions available from Clinical Investigation Service, extension 8951.)

(3) A detailed research protocol, usually a protocol issued by the manufacturer of the product being clinically evaluated.

(4) A bibliography of pertinent information pertaining to the results of previous applications.

(5) A completed FDA Form 1573.

(6) Location and diagram of laboratory facilities and a detailed description and inventory of radiation detection instrumentation and its intended use.

(7) The provisions of AR 40-7 apply to the use of investigational new drugs clinically in human volunteers. The applicant must obtain written approval of the Army Investigational Drug Review Board in accordance with that regulation. Investigational drugs are defined as: "A new drug, not yet approved by the Commissioner of Food and Drugs, Department of Health, Education and Welfare for general use by the public as a safe and efficacious drug, and that is proposed by clinical study under Department of the Army auspices after adequate preclinical information has been obtained."

DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGCEN.

REFERENCE OR OFFICE SYMBOL	SUBJECT
HSF-PM-HP	Clarification of Radioisotope Committee Procedures for Non-Human Uses

TO Radioisotope Committee FROM RPO DATE 27 Feb 79 CMT 1

LT CULLINGS/mw/3926

1. In order to facilitate the approval of procedures for non-human users at FAMC, it is recommended that the Radioisotope Committee approve the following clarification of policy, such approval to be included in our application for NRC License renewal:

a. In the case of non-human use of radioisotopes, the RPO shall have the authority to approve minor changes to radioisotope procedures on a temporary basis.

b. In the case of a minor change, the RPO will require a DF documenting the change from the user involved and will present the change for formal approval at the next Radioisotope Committee meeting. The definition of a "minor change" will include changes in the compound being labelled, increases in animal dosages beyond the authorized limits, and other changes in isotope procedure that do not present additional hazards of airborne or spreadable contamination.

c. Changes which are deemed insignificant by the RPO will not be subjected to this procedure.

d. If there is any question as to how or whether a change to non-human use procedure should be documented, or whether a proposed change is "minor", the RPO will consult with the Radioisotope Committee Chairperson to make the determination.

2. The above, if approved, shall stand as a clarification of FAMC Reg 40-604, Radiation Safety, Appendix A, and shall be a condition of our application for renewal of NRC License 05-00046-13.

Harry M. Cullings

HARRY M. CULLINGS
LT, MSC
Radiation Protection Officer

ITEM 15

Appendix B of FAMC Reg 40-604
Responsibilities of Principal Users of Radioactive Material

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

APPENDIX B
RESPONSIBILITIES OF PRINCIPAL USERS OF RADIOACTIVE MATERIAL

1. Purpose. The purpose of this appendix is to delineate the responsibilities and authority of a principal user of radioactive material.

2. Definitions.

a. Principal user. See definition, paragraph 3f, Appendix A to this regulation.

b. Co-worker. See definition, paragraph 3g, Appendix A to this regulation.

c. Trainee. See definition, paragraph 3h, Appendix A to this regulation.

d. Technician. See definition, paragraph 3i, Appendix A to this regulation.

3. Specific responsibilities.

a. Become thoroughly familiar with the contents of this regulation prior to the use of radiation sources.

b. Obtain and use radiation sources only as authorized by this regulation.

c. Take adequate precautionary measures to protect themselves and others from unwarranted exposure to radiation.

d. Seek advice and assistance from the Radiation Protection Officer when in doubt concerning the safety of an operation.

e. Prescribe rules, procedures, or protocols for the use of radioactive materials under their control to insure proper and safe use. These rules will be made available to any radiation worker in that area and will be furnished to the Radiation Protection Officer upon request. (See Section I to this Appendix for a list of radiation laboratory safety rules.)

f. Insure that all personnel working under their FAMC authorization or in their area of responsibility are familiar with the specific practices to be followed or avoided in the interest of radiological safety. The Radiation Protection Officer will assist in providing instruction in radiation safety upon request.

g. Preclude the misuse of radioisotopes and radiation-producing devices by unstable or irresponsible personnel who might endanger themselves or others by their conduct.

h. Insure that all rules, procedures, and practices of radiological safety are vigorously followed in the work area.

i. Seek the assistance of the appropriate supervisors if assistance in obtaining cooperation and compliance is needed. Although the Radiation Protection Officer is available to provide necessary technical advice on matters of radiological safety, enforcement of regulations and rules is basically the responsibility of the immediate supervisor. All disputes should be resolved at the lowest possible level.

j. Report to the Radiation Protection Officer all known or suspected over-exposures to radiation. The overexposed individual shall cooperate in any and all attempts to evaluate his radiation exposure.

k. Maintain a current inventory of the quantity (in curies or fraction thereof) of radioactive material on hand to be readily available to the Radiation Protection Officer upon request.

l. Provide information and assistance to the Radiation Protection Officer that is necessary for the completion of adequate radiation protection surveys. If classified or sensitive information must be discussed, it must be clearly identified so that it will not become subject to compromise.

m. Maintains responsibility to the FAMC Radioisotope Committee for violations of this regulation by personnel working under their FAMC authorization. The Radiation Protection Officer will report all cases of this nature to the Committee whenever appropriate corrective actions are not initiated by the principal user or when violations are repeated or flagrant. The principal user will be invited to the meeting at which the matter is discussed.

SECTION 1
LABORATORY RULES FOR THE USE OF RADIOACTIVE MATERIALS
(Responsibilities of Principal Users of Radioactive Materials)

1. Film badges will be worn at all times, whole body badge, wrist and/or finger badge, when working with radioactive materials or when within a radiation area.

2. Film badges will not be tampered with, nor will film cassettes be removed from the holders nor will they be purposely or maliciously exposed to sources of radiation.

3. Film badges will not be stored in areas other than those designated by the Radiation Protection Officer.

4. Film badges will not be taken home or worn outside the confines of FAMC without the express consent of the Radiation Protection Officer.

5. No food or drink will be consumed nor will cosmetics be applied within any area where radioactive materials are stored or used.

6. No smoking within any radiation area.

7. Do not store any food products or drinks (to include eating utensils or food or drink containers) within any radiation area.

8. Do not use laboratory glass ware or equipment for the preparation or consumption of food or drink.

9. Laboratory coats or aprons and protective disposable gloves will be worn when working with radioactive materials.

10. Protective disposable gloves will be disposed of in the radioactive waste container.

11. Hands will be washed thoroughly following the handling of radioactive materials and hands will be monitored immediately following washing.

12. Hands, clothing, and shoes will be monitored at the completion of each work period, and prior to departing the area where radioactave materials are stored or handled.

13. Hands and clothing will be monitored prior to eating, drinking, or smoking.

14. Syringe shields will be used for the preparation and administration of radioactive materials to patients, except in circumstances where their use may compromise the patient's well being.

15. Radioactive materials will be transported in shielded containers.

16. Assay each patient dose in a dose calibrator prior to administration. Do not use any dose which varies more than 10% from the prescribed or calculated dose.

17. Pipetting by mouth is strictly prohibited.

18. All work surfaces will be covered with absorbant material. This material will be monitored and disposed of at the completion of each work day. Non-contaminated material may be disposed in routine waste.

19. All uncovered surfaces will be monitored at the completion of each work day.

20. Unnecessary materials and equipment will not be stored in radiation areas.

21. Radioactive waste will be disposed of in the designated containers. Needles and syringes will be clipped in accordance with the appropriate regulations.

22. Survey generator, kit preparation, and injection areas at the end of each work day. Decontaminate as necessary.

23. Isolate spills and begin decontamination immediately. Notify the Health Physics Section whenever a spill has occurred and minimize the number of personnel involved in decontamination.

24. Whenever a spill occurs, protective clothing will be donned prior to carrying out decontamination procedures (apron and gloves).

27. To preclude the buildup of contamination, the laboratory shall be surveyed by the occupants daily.

ITEM 15

Nuclear Medicine Standard Operating Procedure

(1) Preparation of Therapeutic Iodine Dose

(2) Opening of Sealed Containers

Clinical Investigation Service Standard Operating Procedure

(1) Iodination Procedure

7. DISPENSING OF I-131:

a. The following special instructions, as well as the general safety rules, will be followed by personnel dispensing I-131 radiopharmaceuticals.

b. All I-131 doses will be drawn inside the chemical hood, located in the nuclear pharmacy.

c. The protective window will be closed as much as practicable.

d. Doses will be drawn into a syringe and assayed. (the dose will be within ±10% of prescribed dose at the time of administration)

e. The dose will be placed in a vial covered with parafilm. The vial will be labeled with the isotope, activity, date, and time.

f. The vial will be placed in a shield and stored in the chemical hood, in the nuclear pharmacy, until it is administered to the patient.

g. Administration will occur in the isotope administration area of the Nuclear Medicine Clinic.

h. I-131 solutions will be administered by having a patient drink them through a straw while a technologist flushes the vial with non-radioactive water. Usually 30 - 60 ml. of water will be used to flush the vial.

i. After administration the vial will be assayed in the dose calibrator to insure that the patient received the required amount of activity.

j. The vial and straw will be disposed of in accordance with Annex A.

k. The technologist administering the dose and any personnel present who could have been contaminated by the administration will receive a thyroid uptake determination within the next 24 to 48 hours. (see Nuclear Medicine Service SOP, Annex I)

Standard Operating Procedure

Opening of Sealed Containers

1. Don protective gloves.
2. Place absorbant pads on surface area in fume hood, behind lead bricks.
3. Transfer container to fume hood.
4. Remove bottle or container from lead pig.
5. Tilt the container so that if a spray is created it will be directed away from the body when the cap is removed.
6. Place container in lead pig to insure against spillage.
7. Using syringe and needle, or pipette, remove desired volume.
8. If possible, replace capwhile container is in lead pig.
9. Return container to storage area.
10. Remove absorbant pads and place in radioactive waste.
11. Remove protective gloves and place in radioactive waste.
12. Monitor fume hood for contamination.

Clinical Investigation Service
Special Standard Operating Procedure
Iodination Procedure

In addition to normal lab SOP and radiation procedures for handling liquid radioactive materials, the following points will be observed when performing the iodination procedure:

1. Iodination will be performed by the Chloramine-T method. Chemical protocol will be based on the 24 May 1973 protocol for Walter Reed Army Medical Center, which prescribes a pH of 7.4 for the procedure. Any new chemical protocol must be approved by the FAMC Radioisotope Committee.

2. All steps involving iodination will be carried out in a fume hood with at least 150 fpm face velocity. At present the only two suitable hoods are those in Rm 211 and Rm 215 of Bldg 600.

3. All Personnel performing or assisting in this procedure will receive bioassay for I-125 in accordance with the FAMC Bioassay Program.

4. Only those persons who are authorized by the Radiation Protection Officer for iodination will physically accomplish or assist in this procedure.

ITEM 15

Nuclear Medicine Standard Operating Procedure

(1) Preparation and Assay of Patient Doses

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5. CALCULATION OF PATIENT DOSES:

a. DA form 4574-R will be completed prior to drawing any patient dose. The calculations necessary for completion of this form are described below.(see also Annex F)

b. The present Assay (mCi/ml) is calculated by applying the decay equation to the initial assayed activity and the elapsed time.

$$A_t = A_o\, e^{(-.693\ \frac{t}{T})}$$

Where: A_t is the activity at time "t" (present).

A_o is the activity at time zero

e is the natural antilogrhythm

t is the elapsed time since A_o

T is the half-life of the isotope concerned

c. The volume to be drawn is calculated as follows:

$$\text{Vol. drawn} = \frac{\text{Activity Desired}}{\text{Specific Activity } (A_t)(\text{mCi/ml})}$$

d. After drawing the patient dose is assayed in the dose calibrator to ensure the dose is within ±10% of the prescribed dose.

6. Calculation of Pediatric doses:

a. Pediatric dosage will be calculated by weight. The normal adult weight is considered to be 70 Kg.

b. Calculation

$$\text{Dose}_{ped} = \text{Norm Adult Dose } (\frac{\text{Patients Weight (Kg)}}{\text{70 Kg.}})$$

Note: either the dose as calculated above or the minimum dose, as indicated by the physician, whichever is greater will be dispensed.

ITEM 15

Standard Operating Procedure: Movement of Radioactive Materials

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Standard Operating Procedure

Movement of Radioactive Materials

1. The following rules apply to the movement of radioactive materials between rooms and in hallways and corridors at FAMC:

a. Care will be taken to insure that loose or liquid materials are sealed against spillage.

b. Shielding (pigs or shielded cart) will be used to reduce personnel exposure as low as is reasonably achievable. Questions about adequacy of shielding will be resolved by the RPO.

2. The following additional rules apply when radioactive material is moved from the immediate laboratory area (e.g., when Nuclear Medicine Service moves doses to the wards for portable scans):

a. A thin window geiger instrument will be carried along. Any suspected spills, contamination or leakage will be immediately monitored. Positive areas will be immediately marked and reported to the Health Physics Office.

b. The technician in charge will be informed by the user (physician) that he/she (technician) is held strictly responsible for the physical security of patient doses until they are administered.

ITEM 15

Appendix D of FAMC Reg 40-604
Control Measures and Protection Standards for Radiation Exposure

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APPENDIX D

CONTROL MEASURES AND PROTECTION STANDARDS FOR RADIATION EXPOSURE

1. References

a. Title 10, Code of Federal Regulations, Part 20, U.S. Nuclear Regulatory Commission Rules and Regulations.

b. AR 40-14, Control and Recording Procedures, Occupational Exposure to Ionizing Radiation.

c. AR 385-30, Safety Color-code Markings and Signs.

2. Applicability. The definitions and limitations stated in this Appendix are peacetime standards for occupational exposure of personnel to ionizing radiation. Occupational exposure to ionizing radiation is that exposure incurred as a result of an individual's employment or duty. No portion of this Appendix shall be interpreted as limiting the intentional exposure of an individual to radiation for the purpose of medical diagnosis or medical therapy of that individual.

3. Definitions and requirements for restricted areas.

a. Restricted area.

(1) Definition.

(a) Any area to which access will be limited by the Radiation Protection Officer and in which precautionary measures are taken for the purpose of protecting individuals from exposure to ionizing radiation, radioactive materials, or both.

(b) Any area so designated by the Radiation Protection Officer.

(2) Requirements.

(a) Restricted areas will be posted by the Radiation Protection Officer.

(b) A controlled area will be under the supervision of an individual authorized by the Radiation Control Committee to use sources of radiation in that area.

(c) The restricted area sign will read:

"RESTRICTED AREA"
"Persons who occupy this area for more than 10 hours per week must be registered with the Radiation Protection Officer"

b. Radiation area.

(1) Definition. Any area, accessible to personnel, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose equivalent in excess of 2 millirem, or in any five consecutive days a dose equivalent in excess of 100 millirem.

(2) Requirement. Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

"CAUTION"
"RADIATION AREA"

c. High radiation area.

(1) Definition. Any area accessible to personnel in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose equivalent in excess of 100 millirem.

(2) Requirements.

(a) A high radiation area shall not be established without the approval of the Radiation Protection Officer or his representative except in an emergency.

(b) Each high radiation area established for more than 30 days shall be equipped with control devices in accordance with paragraph 20.203(c)(2), 10 CFR 20.

(c) Except in an emergency, no individual shall enter a high radiation area until the area has been monitored by the Radiation Protection Officer and approval for his entry has been given.

(d) No individual shall enter or remain in a high radiation area unless personnel are immediately available in the vicinity to render assistance.

(e) Each individual who enters a high radiation area will be on a monitoring program.

(f) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

"CAUTION"
"RADIATION AREA"

d. Airborne radiation area.

(1) Definition. Any room, enclosure, or operating area in which airborne radioactive materials exist in concentration in excess of amounts specified in Appendix B, Table 1, Column 1, Title 10, Code of Federal Regulations, Part 20,

or any room, enclosure, or operating area in which airborne radioactive material exists in concentrations which, averaged over a number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in the above referenced Code of Federal Regulations (from paragraph 3-1e, AR 385-30).

(2) Requirements.

(a) An airborne radioactivity area shall not be established without approval of the Radiation Protection Officer except in an emergency.

(b) The Radiation Protection Officer shall direct the use of respiratory protective devices, ventilation control measures, and other appropriate actions within the airborne radioactivity areas.

(c) Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

"CAUTION"
"AIRBORNE RADIOACTIVITY AREA"

e. Areas where radioactive material is present.

(1) Definition. Any area where radioactive material is stored. The provisions of this paragraph apply to materials which have been procured and are useful because of their radioactive component including natural Uranium or Thorium compounds used for histological staining.

(2) Each area, room or principal container in which radioactive material is stored or used shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

"CAUTION"
"RADIOACTIVE MATERIAL(S)"

(3) Samples, working solutions, laboratory standards, check sources, etc., must be labeled, segregated, or otherwise identified in such a manner that all personnel in the area recognize that radioactive material is present in the object. Radioactive marking tape may be used for this purpose. However, beakers, flasks, test tubes, and other laboratory containers used transiently in laboratory procedures are exempt from labelling requirements.

f. Contaminated areas.

(1) Definition. Any area, including work areas, which are contaminated with radioactive material to levels in excess of values published in Section 1 to Appendix F of this regulation (Contamination Control and Decontamination Operations).

(2) Requirements.

(a) Any area which may routinely become contaminated during experimental procedures may be posted conspicuously with a sign or signs bearing the radiation caution symbol and the words:

"CAUTION"
"POTENTIALLY CONTAMINATED AREA"

(b) Any area which is contaminated may be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

"CAUTION"
"CONTAMINATED AREA"

(c) All areas designated as "Contaminated Areas" or "Potentially Contaminated Areas" will always be regarded as heavily contaminated and must be surveyed by the Radiation Protection Officer following use and decontamination in order to be considered free of contamination.

g. Special areas of concern.

(1) At the discretion of the Radiation Protection Officer, dose rates may be posted for informational purposes at any point.

(2) Sinks through which radioactive material may be discharged into the sanitary sewer system shall be conspicuously posted with the radiation caution symbol and the words:

"CAUTION"
"RADIOACTIVE MATERIAL DISPOSAL SINK"

(3) All laboratory receptacles for radioactive waste shall be conspicuously posted with the radiation caution symbol and the words:

"CAUTION"
"RADIOACTIVE WASTE"

(4) Equipment containing or likely to contain radioactive material, and equipment requiring special precautions to perform specific tasks, will be posted with a sign stating that approval of the Radiation Protection Officer is required before any maintenance or repair of this item is initiated.

4. Exposure of individuals to radiation in restricted areas.

a. In accordance with paragraph 20.101, 10 CFR 20, and AR 40-14, no user shall possess, use, or transfer radioactive material (for the purpose of this regulation, any source of ionizing radiation) in such a manner as to cause any individual in a restricted area to receive a dose in excess of the limits specified as follows:

(1) The accumulated dose to the whole body, head and trunk, active blood-forming organs, gonads, or lens of the eye, shall not exceed:

(a) 1.25 rem in any calendar quarter, nor

(b) 5(N-18) rem total limiting dose, where N equals the individual's present age, at their last birthday.

(2) The accumulated dose to the skin of the whole body or to the thyroid shall not exceed:

(a) 10 rem in any calendar quarter, nor

(b) 30 rem in any calendar year.

(3) The accumulated dose to the hands and forearms, or to the feet and ankles, shall not exceed:

(a) 25 rem in any calendar quarter, nor

(b) 75 rem in any calendar year.

b. No individual under 18 years of age shall be occupationally exposed to ionizing radiation in excess of that allowed to any individual in the population at large (500 millirem in any calendar year).

c. Notwithstanding the above criteria, an emergency (once in a lifetime) dose of 25 rem to the whole body or a major portion thereof is authorized, providing such exposure is necessary to save life or perform an unusual task which, if left uncorrected, would have the potential for seriously endangering health and/or valuable property. Except under the most unusual circumstances, the exposure will be authorized in advance by the Radiation Protection Officer, and each individual so exposed will wear a self-reading pocket ionization chamber capable of indicating an exposure up to 50 Roentgens, in addition to other personnel monitoring devices (see pages 99 to 101, NCRP Report Number 39, Basic Radiation Protection Criteria).

d. When dosimetry indicates that an individual may have received greater than 200 millirem whole body exposure; exposure to an unusual concentration of airborne radioactive material; or the individual believes he may have been exposed to excessive ionizing radiation, the Radiation Protection Officer will investigate the circumstances of the exposure. A written report of the investigation will be prepared.

e. When it is determined that an individual may have received a dose of ionizing radiation in excess of the limits stated in paragraph 4a and 4b above, or has been exposed to airborne concentrations of radioactive material in excess of 25% of the

amounts specified in Appendix B, Table 1, Column 1, 10 CFR 20, a report of the findings will be made to the FAMC Radioisotope Committee for recommendation for corrective action to be taken. Reports of investigation of overexposures and corrective action will be submitted through Health Services Command, Fort Sam Houston, Texas, to The Surgeon General and the USNRC in compliance with pertinent directives.

f. The exemption of medical exposure from consideration relative to permissible exposure limits of the Appendix apply only to the patient. All other personnel, such as physicians and technicians administering exposures, are subject to the permissible limits above.

5. Accidental exposure to ionizing radiation. The specific procedures and responsibilities relating to the accidental exposure of personnel to known or suspected overexposures are delineated in Appendix T of this regulation.

a. Internal exposure. All persons who are known or suspected to have been internally exposed to quantities of radioactive material in excess of 10% of the amounts specified in Appendix C, 10 CFR 20 (Section I to Appendix T of this regulation), shall be reported to the Radiation Protection Officer.

b. External exposure. All persons who are known or suspected to have been externally exposed to radiation levels in excess of those listed in paragraph 4a and 4b above, shall be reported IMMEDIATELY to the Radiation Protection Officer.

ITEM 18

Appendix J Form for Waste Disposal

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APPENDIX J

WASTE DISPOSAL

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

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

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

____ Other (specify): _____

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

____ Returned to the manufacturer for disposal.

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

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

____ Other (specify): _____

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

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

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

____ Other (specify): _____

4. The commercial waste disposal service used will be

See detail below.

(Name) (City, State)

NRC/Agreement State License No. _____

4. Low level RIA waste (counting vials, absorbant pads, etc.) is collected by Health Physics and packaged in barrels for disposal.

Some of this waste has a liquid component: beta scintillation counting fluid contained in sealed glass vials. Barrels containing this liquid component are packaged with absorbent material in accordance with the specifications of 49CFR and other applicable regulations.

FAMC currently does not control the choice of disposal contractor. Disposal is accomplished by bulk lots through ARRCOM, ATTN: DRSAR-MAY-MC, Rock Island Arsenal, Rock Island, Illinois, 61201. This agnecy chooses a disposal contractor and provides FAMC with instructions and funding authorization for disposal.

ITEM 19

Therapeutic Use of Radiopharmaceuticals

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19. The following information is submitted regarding the therapeutic use of radiopharmaceuticals by Nuclear Medicine Service.

a. Methods for preparation and administration of therapeutic I-131 doses are presented in the SOP enclosed here as (Tab C for Item 15).

b. Contamination control procedures are specified in Appendix P of FAMC Reg 40-604, enclosed here as Tab A.

c. Procedures for surveys are included in the reference above, Tab A (on the ward); and (Tab D of Item 15)(Nuclear Medicine Lab).

d. Instructions to Nursing Staff are in Section II of Appendix P, FAMC Reg 40-604, Tab A.

e. Waste disposal procedures are covered in Tab A. There is an exception to the Licensing Guide (Appendix K) in that urine is not collected for therapy patients. All patient excreta are discharged into the sanitary sewer system as authorized in 10CFR20.303.

FAMC operates a sewage treatment plant on the installation. The treated effluent is held in holding ponds or used to water the golf course on the installation. There is no direct discharge to the Colorado environs.

f. Procedures for Emergency Surgery and Death are covered in Sections III and IV of Appendix P to FAMC Reg 40-604, Tab A.

g. Procedures for release of patients are covered in Section V of Appendix P to FAMC Reg 40-604, Tab A.

h. Bioassay requirements are included in the FAMC Bioassay Program. See (Tab A of Item 23).

Tab A

ITEM 19

Appendix P of FAMC Reg 40-604
Radiation Protection Aspects of Patient Care

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APPENDIX P
RADIATION PROTECTION ASPECTS OF PATIENT CARE

1. Responsibilities.

a. The Radiation Protection Officer, FAMC, is responsible for providing full-range radiation protection support throughout FAMC.

b. The Commander, FAMC, provides such guidelines as are necessary to insure adequate protection for medical treatment personnel involved in patient care who are occupationally exposed to ionizing radiation.

2. Specific requirements.

a. Individuals who are occupationally exposed to radiation from radioisotopes or x-ray producing devices will wear film badges unless specifically exempted by the Radiation Protection Officer.

b. Personnel, equipment, linen and facilities will be monitored for radioactive contamination following any procedure in which the possibility of contamination exists.

c. Dressings, etc., destined for disposal will be monitored and disposed of as radioactive waste when warranted.

d. The Radiation Protection Officer will not impede patient care, but is expected to make recommendations to minimize the accumulated dose to medical personnel and patients who are not being treated with radiation.

e. Patients will not normally be discharged from the hospital with more than 30 mCi of radioactive material remaining in the body. The specific requirements of USNRC License 05-00046-13 are given in paragraph 7, Section 5 of this Appendix.

f. Guidance on various areas of patient care are described below:

(1) Radiation Protection Aspects of Nursing Care of Radiation Therapy Patients with SEALED Sources (see Section I to this Appendix).

(2) Radiation Protection Aspects of Nursing Care of Radiation Therapy Patients with NON-SEALED Sources (see Section II to this Appendix).

(3) Death - Radiation Protection Procedures (see Section III to this Appendix).

(4) Radiation Protection Aspects of Surgery and Autopsy (see Section IV to this Appendix).

(5) Radiation Protection in the Therapeutic Administration of Radioactive Material (see Section V to this Appendix).

(6) Management of Radioactive Casualties (see Appendix Q to this regulation).

SECTION I
RADIATION PROTECTION ASPECTS OF NURSING CARE OF RADIATION THERAPY PATIENTS WITH SEALED SOURCES
RADIATION PROTECTION ASPECTS OF PATIENT CARE

1. Purpose. The purpose of this Section is to familiarize the nursing staff with their responsibilities to the patient and themselves in the prevention of unnecessary exposure to radiation.

2. General.

a. A sealed source has the radioactive material encapsulated in a metal tube which is sealed. Once this source has been removed from the patient, there is no longer a source of radiation in the patient. There is no contamination on the linen, utensils, or other hospital equipment unless the seal is broken.

b. In the event of major surgery, transfer of the patient, or death of the patient, notify the Radiation Protection Officer (extension 3826/3916) AND the physician who administered the radioactive material.

3. Specific guidance.

a. Whenever possible, place the patient in a private room with the bed near the outside wall of the room. When it is necessary, two radiation therapy patients may be placed in the same room. A non-radiation therapy patient should not be in the same room with a radiation therapy patient. If private rooms are not available, the Radiation Protection Officer must be contacted to assist in establishing bed location.

b. Consistent with adequate care for the patient, carry out only minimal nursing procedures close to the patient. If the patient's clinical status requires constant observation, rotate personnel required to perform adequate nursing care in order to minimize exposure to personnel. The patient's bed should be approached, within the 5 mR/hr line, only when required by nursing duties.

c. Whenever possible nursing care should be provided from behind radiation shield when provided.

d. Wear YOUR film badge when entering the area. DO NOT use the film badge issued to another employee. Film badges may be obtained by calling the Radiation Protection Officer (extension 3826/3916).

e. Personnel are not to remain in the room unless engaged in a specific activity. Custodial, utility, maintenance, and food service workers should not enter the room unless they receive permission and instructions from the ward nurse.

f. A television set, telephone, books, or other items for the patient's entertainment may be provided for the patient.

g. Excreta, linens, and other equipment may be handled in the usual manner.

h. Special handling of the food tray is not required.

i. In the event of a suspected loss or dislodgment of the sealed source:

(1) Notify the physician who administered the source.

(2) Notify the Radiation Protection Officer (extension 3826/3916).

(3) Do not remove any containers or linen from the room, flush the toilet, or use the sink.

(4) The radioactive source must be handled only with forceps.

(5) Do not allow dislodged sources to remain in contact with patient.

j. The patient may have visitors if the physician thinks that they will contribute to the patient's well being. The visitors should stay on the "safe" side of a line indicated on the floor by the Radiation Protection Officer.

k. If the patient should die, notify the physician who administered the source. The source will be removed before the body is taken to the morgue.

l. The Radiation Protection Officer will:

(1) See that the bed is placed to minimize exposure to adjacent areas.

(2) Establish safe distance line as necessary (usually 5 mR/h).

(3) Determine exposure rate at surface, 30 cm 1 meter, and 2 meters as necessary.

(4) Advise the patient of potential hazards to visitors.

(5) Prepare and post information packet (see Section V, Appendix P, paragraph 6b(4)).

SECTION II
RADIATION PROTECTION ASPECTS OF NURSING CARE OF RADIATION THERAPY PATIENTS WITH NON-SEALED SOURCES
RADIATION PROTECTION ASPECTS OF PATIENT CARE

1. Purpose. The purpose of this Section is to familiarize the nursing staff with their responsibility to the patient and themselves in the prevention of unnecessary exposure to radiation.

2. General.

a. A non-sealed radioactive source is a radioactive compound administered directly into the patient. The source material will remain in the patient until it decays by half-life or is excreted. Contamination of linen, utensils and other hospital equipment is possible.

b. In the event of major surgery, transfer of the patient, or death of the patient, notify the Radiation Protection Officer (extension 3826/3916) AND the physician who administered the radioactive material.

3. Specific guidance.

a. Whenever possible, place the patient in a private room with the bed near the outside wall of the room. When necessary, two radiation therapy patients may be placed in the same room. A non-radiation therapy patient should not be in the same room with a radiation therapy patient.

b. Consistent with adequate care for the patient, carry out only minimal nursing procedures close to the patient. If the patient's clinical status requires constant observation, rotate personnel required to perform adequate nursing care in order to minimize exposure to personnel. The patient's bed should be approached only when required by nursing duties, i.e., remain beyond 5 mR/hr line when possible.

c. Wear YOUR film badge when entering the area. DO NOT use the film badge of another employee. Film badges may be obtained by calling the Radiation Protection Officer (extension 3826/3916).

d. Personnel are not to remain in the room unless engaged in a specific activity. Custodial, utility, maintenance, and food service personnel should not enter the room unless they receive permission and instructions from the ward nurse.

e. A television set, telephone, and books may be provided the patient.

f. The food tray will be prepared entirely with disposable components. The tray will be disposed of as waste within the patient's room. Uneaten food WILL NOT be given to other patients or staff members.

g. The Radiation Protection Officer will monitor the patient area and will indicate a "safe distance" line for visitors, if it is determined by the physicians that visitors are necessary. Visitors should stay on the "safe" side of the line indicated on the floor.

h. Necessary contamination control measures are very similar to isolation techniques.

i. Cover the mattress and pillow on the bed with plastic or rubber material.

j. Wear gloves when changing bed linen, dressings, etc.

k. The patient must wear hospital pajamas.

l. Place a plastic-lined waste basket and linen hamper in the patient's room.

m. Place waste, soiled liner, etc., in the designated containers for monitoring and disposal by the Radiation Protection Officer.

n. Personal items for patient care (thermometer, bedpan, etc.) will be kept in the patient's room. Bath water will be disposed of in the commode.

o. Ambulatory patients will use the commode in their room.

p. Diagnostic samples of blood, urine, and feces should only be obtained when authorized by the radiotherapist.

q. The urine excreted by the patient is radioactive. Spills, bedwetting, or any accident with urine are radiation hazards. Wear gloves. In the event of an accidental spill of urine, put on gloves, absorb material, then place the material in the designated waste container. Notify the Radiation Protection Officer.

r. Collect [illegible] by inserting AND the Radiation Protection Officer for [illegible] clogged drain may be a radiation hazard.

s. If the patient dies, staff [illegible] who administered the source AND the Radiation Protection Officer. The body will not be removed from the ward until the Radiation Protection Officer has taken the appropriate protective measures to be taken during transport of the body.

t. The room will not be returned to normal use, i.e., another patient placed in the room, until cleared by the Radiation Protection Officer.

[illegible]CTION III
[illegible] PROTECTION PROCEDURES
[illegible] ASPECTS OF PATIENT CARE

1. Applicability. [illegible] to the management of remains of patients who have [illegible] radiation therapy with radioactive implants or unsealed radioisotopes. If the [illegible] within the body is less than 5 mCi, i.e., if there is no Radiation Protection Instruction Card in the patient's Kardex file), the body will be handled [illegible] for the presence of the radioactive material.

2. Radioactive [illegible]. [illegible] has been treated with a radioactive implant, the [illegible] will be followed:

a. Notify [illegible] administered the implant. The implant will be removed [illegible] morgue.

b. [illegible] Officer (extension [illegible]) for any [illegible] of the remains and return of the room [illegible]

[illegible] removed from the body, the remains [illegible]

[illegible] the body, e.g. radon, [illegible] below.

3. [illegible] has been receiving radiation therapy [illegible], the [illegible] outlined below [illegible]

[illegible] material

[illegible]

[illegible] hospital equipment for radioactive [illegible] return to general use.

[illegible] items for disposal or decontamination, [illegible]

[illegible] signs from the patient's room.

4. Administrative requirements. To insure the prompt identification of radioactive remains and to facilitate the minimizing of radiation exposure of the staff, the following administrative procedures will be followed:

a. The "CAUTION - RADIOACTIVE MATERIALS" label affixed to the outside of the chart will remain in place until all radioactive material is removed from the body.

b. The tag located in the Kardex File bearing the radiation warning symbol and the words, "CAUTION - RADIOACTIVE MATERIALS, this patient's body contains a significant quantity of radioactive material as specified in Chapter 3, NCRP Report Number 37," will be attached to the body in the same manner as the tag contained in the mortuary pack.

c. A similar tag or label will be attached to the outside of the shroud by the attending Radiation Protection Officer.

d. If the body contains residual quantities of radioactive material, the Radiation Protection Officer or his representative will complete and sign one of the following statements in accordance with Appendix V, NCRP Report Number 37. This statement will be attached to the Death Certificate for transmittal to the Funeral Director by the Directorate of Patient Administration, FAMC.

(1) Report on radioactivity.

TO: Funeral Director

FROM: Radiation Protection Officer
Fitzsimons Army Medical Center
Denver, Colorado 80240

This body contains residual radioactive material. No special precautions are necessary beyond normal handling procedures are employed.

RADIATION PROTECTION OFFICER
Fitzsimons Army Medical Center
DATE: [illegible]

(2) Report on radioactivity.

TO: Funeral Director

FROM: Radiation Protection Officer
Fitzsimons Army Medical Center
Denver, Colorado 80240

This body contains a significant amount of radioactive material. The following special precautions are recommended:

_____

_____

_____

RADIATION PROTECTION OFFICER
Fitzsimons Army Medical Center
DATE _____

c. References.

a. NCRP Report Number 37, Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides.

b. Quimby, E.N., and Feitelberg, S., Radioactive Isotopes in Medicine and Biology, Lea and Debiger, Philadelphia, 1963.

SECTION IV
RADIATION PROTECTION ASPECTS OF SURGERY AND AUTOPSY
RADIATION PROTECTION ASPECTS OF PATIENT CARE

1. General.

a. The Radiation Protection Officer will provide direct support to surgery and autopsy on patients whose bodies contain radioisotopes.

b. The principal guidance for surgeons, pathologists, and funeral directors on this subject is contained in NCRP Report No. 37, a copy of pertinent sections may be obtained from the Radiation Protection Officer.

c. Radiation protection support and/or advice regarding radiation protection during surgery or autopsy may be obtained by calling:

Duty hours: Extension 3626/3916.

2. Special requirements.

a. Prior to the surgery (autopsy) the physician who administered the radioactive material should meet with the assigned surgeon (pathologist) and the Radiation Protection Officer. The probable residual quantity of radioactive material within the body will be estimated. The radiation protection aspects of the surgery (autopsy) procedure will be estimated.

b. If the anticipated exposure to the surgeon (prosector) and his assistants is considered to be prohibitive, it may be necessary to delay the procedure to allow for a "cooling off" of the radioactive material in the body, or rotate the personnel performing the procedure to preclude overexposure.

c. Personnel engaged in and supporting surgery (autopsy) will wear film badges if the patient contains radioisotopes, unless exempted by the Radiation Protection Officer.

d. Personnel, equipment, linen, and facilities will be monitored for radioactive contamination following the procedure when the possibility of contamination exists.

e. Tissues, dressings, etc., destined for disposal will be monitored and disposed of as radioactive waste, when warranted.

f. The Radiation Protection Officer will not impede procedures, but are expected to make recommendations to minimize the accumulated dose to the surgeon (pathologist) and other members of the team.

g. Autopsy.

(1) At the completion of the autopsy, the physician who administered the radioactive material will inform the Radiation Protection Officer of the probable residual quantity of radioactive material within the body, based on the body fluids, tissues, and organs which were removed.

(2) The Radiation Protection Officer will review the statement which has been executed for delivery to the Funeral Director to determine if the warning is still applicable.

SECTION V
RADIATION PROTECTION IN THE THERAPEUTIC ADMINISTRATION OF RADIOACTIVE MATERIAL
RADIATION PROTECTION ASPECTS OF PATIENT CARE

1. Purpose. The purpose of this Section is to specify the duties of the Radiation Protection Officer in the prevention of unwarranted exposure to nursing personnel, visitors, and those who occupy areas adjacent to the patient being treated.

2. Notification of therapeutic administration.

a. Sealed sources.

(1) The radiotherapist will provide the radiological physicist with the following information: The type and quantity of sealed sources, the applicator to be used and its loading arrangement, the patient's name, date of use, and ward number.

(2) The radiological physicist will load the applicator.

b. Non-sealed sources. The Nuclear Medicine Service will notify the Radiation Protection Officer by telephone (x22s/3916) of the proposed schedule for the administration of the radioactive material.

c. Notification of ward nurse.

(1) The Radiation Protection Officer will notify the appropriate ward nurse of the proposed administration of radioactive material. A copy of Section I and II to Appendix R will be furnished to the ward as appropriate.

(2) The Radiation Protection Officer will obtain from the nurse the names and social security numbers of those persons who will be caring for the therapy patient and will issue film badges to them.

3. Preparation of the radioactive material.

a. Sealed sources. The radiological physicist and the radiation therapy technician should divide the workload between them in order to keep their exposure to a minimum. A bar graph indicating their whole body and wrist exposure should be maintained in order to visualize the workload distribution.

b. Non-sealed sources. Personnel in the Nuclear Medicine Service have specific responsibility for the preparation of non-sealed sources.

4. Sealed source administration.

a. The radiotherapist is responsible for the safe handling of the radioactive material from the time it leaves Radiation Therapy until he returns it.

b. The radiological physicist (extension 8801/3045) will provide assistance.

5. Non-sealed source administration.

a. The Nuclear Medicine Service personnel are responsible for safe delivery of the radioactive material to the ward, and for obtaining sufficient absorbent paper and other protective equipment as indicated by the type of radioactive material.

b. A Radiation Protection Officer will normally be in attendance during therapeutic administration of unsealed radioactive material.

c. The Radiation Protection Officer will:

(1) Ascertain that the protective materials are located to provide protection medical personnel.

(2) Remain available during the administration for assistance.

d. Following administration, the Radiation Protection Officer will:

(1) Monitor the administering staff and their equipment.

(2) Insure that radioactive laundry and waste containers are in the patient's room and are properly labeled.

(3) Employing a manner which will obtain the desired results without alarming the patient, instruct him/her in procedures for preventing the spread of contamination.

6. Patient care on the ward.

a. When the therapeutic application is performed at a location other than the patient's room, the Radiation Protection Officer will go to the ward as soon as practicable after the patient arrives.

b. The Radiation Protection Officer will:

(1) Ascertain that the patient's bed is placed in a position that will reduce unnecessary exposure of adjacent areas.

(2) Mark on the floor a "safe distance" line of 5 mR/hr.

(3) Advise the patient of the potential hazard to visitors who spend too much time in the room. He will take care not to alarm the patient and will emphasize that the treatment has been prescribed for the patient and not the visitors.

(4) Prepare an information packet to be posted near the doorway to the patient's room. This packet will consist of:

(a) A Radiation Therapy Monitoring Record.

(b) A copy of "Radiation Protection Aspects of Nursing Care of Radiation Therapy Patients with Sealed Sources" or a copy of the Radiation Protection Aspects of Nursing Care of Radiation Therapy Patients with Non-Sealed Sources," as appropriate.

(c) A "CAUTION - RADIOACTIVE MATERIALS" sign.

(5) Place a radiation protection identification card in the patient's Kardex file.

(6) Return to the ward at least once each day to insure that personnel are maintaining good radiation safety practices.

c. Removal of protective markings.

(1) If the patient was treated with a sealed source, the radiation protection restrictions (signs, etc.) will be removed after the source has been removed.

(2) If the patient was treated with a non-sealed source of radioactive material, all radiation protection restriction will remain in effect until the exposure rate at 1 meter is 2mR/hr or less.

(a) The administering physician, as well as the ward officer, should be notified when radiation protection restrictions are removed.

(b) Radioactively-contaminated laundry and waste will be removed from the patient's room and the room will be monitored before it is released for general occupancy.

d. If the patient is not being discharged from the hospital when the residual activity is acceptable, the radiation protection sticker in the Kardex file should be changed to read. See instructions on reverse side of the "CAUTION-RADIOACTIVE MATERIALS" tag in the patient's chart. This tag should be changed to read: "This patient does not require any radiation protection precautions except in the following instances:

(1) In the event of major surgery, notify the Radiation Protection Officer (extension [illegible]) AND the physician who administered the radioactive material. The procedures in Section IV (Radiation Protection Aspects of Surgery and Autopsy) to this Appendix apply.

"(2) In the event of death, notify the Radiation Protection Officer (extension 8801/3045) AND the physician who administered the radioactive material. The procedures outlined in Section III (Death - Radiation Protection Procedures) to this Appendix apply."

7. Discharge of the therapy patient.

a. The US Nuclear Regulatory Commission License for FAMC provides:

(1) Patients receiving radiotherapy with non-sealed Iodine-131, [illegible] on I-125 shall remain hospitalized until the residual activity in the body is 30 millicuries or less.

(2) Patients containing radioactive implants, except Gold-198 or I-125 seeds, shall remain hospitalized until the implant is removed.

b. Normally, radiation therapy patients will remain hospitalized until the residual activity in the body is 30 millicuries or less, regardless of the isotope.

c. Clearances for discharge of the patient may be obtained from the Radiation Protection Officer (extension 3826/3916) or the therapist who administered the material.

d. If the patient is returning to a home where there are young children, an evaluation of the dose to them may be appropriate in determining the discharge date.

e. In no event will a patient be discharged if there is sufficient radioactive material remaining in the body to warrant posting of the patient's room with the radiation warning symbol.

f. In no case will a patient be discharged or released for radiation protection restrictions without having been surveyed by the Radiation Protection Officer, for the explicit purpose of confirming removal of any sealed sources. This information will be entered on the Patient Monitoring Record which is filed by the Radiation Protection Officer.

DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGCEN.

REFERENCE OR OFFICE SYMBOL	SUBJECT
HSF-PM-HP	Visitor Policy for Patients Undergoing Therapy with Radioactive Materials

TO Nursing Service
Wards 3W,4W,6E

FROM RPO

DATE 27 Feb 1979

CMT 1

LT Cullings/dg/3826

1. References: Regulatory Guide 10.8, Nuclear Regulatory Commission, on Medical Licensing, and FAMC Reg 40-604, Radiation Safety, Appendix P, Health Physics Aspects of Patient Care.

2. IAW the references above, it is necessary to document a clarification of our policy on visitors to patients who are undergoing therapy which involves radioactive materials. This statement of policy is a clarification of the references above.

3. Under no circumstances will a pregnant person, or one who suspects oneself of being pregnant, be allowed in the same room of a patient who is undergoing therapy with radioactive materials. Prospective visitors should be asked if they are pregnant.

4. No visitor under the age of 18 will be allowed in the room of a patient undergoing therapy with radioactive materials, unless specifically authorized by the RPO.

Harry M. Cullings

HARRY M. CULLINGS
LT, MSC
Radiation Protection Officer

ITEM 20

Therapeutic Use of Sealed Sources

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

20. The following information pertains to the use of sealed sources to treat patients under the provisions of Group VI on Schedule A, 10CFR35.100.

a. Radiation Therapy Service Isotope Handling Area - this area is used to store and handle sealed sources only, such as Cs-137 sources and I-125 seeds. Location is in the teletherapy room in the northwest corner and north and west walls have been assessed for shielding for the cobalt theletherapy unit. Two inch lead bricks and pigs provide shielding on the south and east sides and a lead safe and L-block are also used.

b. Special precautions for the use of sealed sources are outlined in the SOP from Radiation Therapy Service, Tab A.

c. Special instructions for nursing care of patients being treated with sealed sources are outlined in Section I of Appendix P of FAMC Reg 40-604, enclosed here as (Tab A for Item 19).

d. The extremities of personnel using sealed sources are monitored using Army Film Badges as wrist badges. Further information on personnel monitoring devices is supplied in Item 24.

e. There are two devices available for transporting sealed sources:

(1) A large cart made of 1/8 inch steel covered with 1/16 inch lead which can accomodated lead bricks or pigs for further shielding, and

(2) A small dolly with remotely operated lid, which has 1 3/4 inches of lead shielding.

f. Source accountability is maintained by the use of a source inventory log book. Upon removal of the source, entries are made to reflect date, patient for which used, source(s), source count, initials of user. Upon return of the source(s) to storage, further entries are made to reflect verification of the inventory and source count by the user and user's initials.

Sources are inventoried and log books are checked by the RPO on a quarterly basis.

g. Surveys of the patient and patient's room are conducted during and after treatment. These surveys are prescribed in Appendix P of FAMC Reg 40-604, (Tab A of Item 19).

Tab A

ITEM 20

Standard Operating Procedure: Handling of Sealed Radioactive Sources

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

Radiation Therapy Service
Standard Operating Procedure
Handling of Sealed Radioactive Sources

1. Sources will be manipulated only in the handling area (teletherapy room) with the L-bar and shielding in place.

2. Sources will never be touched; they will be handled carefully with forceps.

3. The user will immediately report to the RPO any suspected leakage or breach of the source's physical integrity.

4. Wrist badges will be worn at all times when handling sources.

5. Cs-137 sources will not be removed from the lead safe without following the procedures for the Source Inventory Logbook.

6. The use of portable shielding and after loading techniques will be maximized in order to reduce exposures ALARA.

ITEM 21

Procedures and Precautions for Use of Radioactive Gases (Xenon-133)

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

21. The following information is submitted in support of the request to use xenon-133:

1. Quantities to be used

a. Patient Information

(1) Number of studies expected per year: 150

(2) Average activitiy per patient: 10 mCi

b. Desired possesion limit: 2 curies

2. Use and storage areas:

a. Areas

(1) Xe-133 will be stored in the Nuclear Medicine Laboratory fume hood behind lead bricks. The diagram is included here as (Tab A for Item 11).

(2) Xe-133 will be used for lung function studies in one of three camera rooms: number 1, 2 or 4. Diagrams of the camera rooms are included as (Tab A for Item 11).

b. Ventilation

(1) Ventilation in the storage area is provided by the fume hood, which has a measured capacity of 200 cfm. Supply of air is through the laboratory access door. There is zero recirculation of the exhausted air.

(2) Ventilation in all cited camera rooms is provided by a window exhaust fan with a capacity of at least 720 cfm. Supply in Camera Room 1 is through the door to the hallway. Supply in Camera Rooms 2 and 4 is from both the hallway access doors and windows at the opposite end of the room - see diagrams referenced above. There is zero recirculation of the exhausted air.

c. Camera rooms are maintained under negative pressure by the window exhaust fans. Studies are conducted only with the fans on and doors and windows opened as in diagrams.

3. Procedures for Routine Use

a. Procedures for routine use of Xe-133 are described in the SOP attached here as Tab A.

b. The machine used to administer and collect Xe-133 is the Nuclear Associates Xe-133 Lung Function Unit, Model 36-001. A copy of the instruction manual for this machine is enclosed here as Tab B.

c. The primary procedures used to reduce leakage are

(1) counseling the patient to obtain maximum cooperation, and

(2) use of nose clamps at all times unless impossible or inconsistent with the patient's welfare.

4. Emergency Procedures

Emergency procedures in case of accidental releases of Xe-133 are detailed in the SOP, attached here as Tab A.

5. Air Concentrations of Xe-133 in Restricted Areas

a. Maximum activity per week = 5X10=50 mCi.

b. Fraction of Xe-133 lost from all sources including leakage and inadvertent release = f = .25.

c. Volume of air available per week for dilution:

(1) Laboratory fume hood: (200cfm) x (168 hrs/wk) x (60 min/hr) = 2,016,000 ft^3

(2) Exhaust fans: (720 cfm/fan) x (40 hrs/wk) (60 min/hr) = 1,728,000 ft^3

d. (1) For the fume hood situation, $\frac{A}{V} \times f = (5.0 \times 10^{4}$ uCi) (.25) $(2.0 \times 10^{6}$ $ft^3)$ $(2.[illegible]$ $ml/ft^3) = 2.2 \times 10^{-7}$ uCi/ml

(2) For the camera rooms, $\frac{A}{V} \times f = (5.0 \times 10^{4}$ uCi) (.25)/ $(1.7 \times 10^{6}$ $ft^3)$ $(2.32 \times 10^{4}$ $ml/ft^3) = 2.6 \times 10^{-7}$ uCi/ml

NOTE: The fume hood in d. (1) above will be operated constantly (168 hr/wk) to vent any possible leakage of stored radioactive materials. The portion of time the camera room fans are to be run will be determined by the calculations above. A running time of one hour per 10mCi study will be used

(see SOP attached here as Tab A). This will allow a factor of 400 - 500% margin of error to account for imperfect patterns of ventilation and still be assured of complying with 10CFR20.103.

6. Methods of Xe-133 Disposal

a. A NONEX brand charcoal filter gas trap is used to absorb the waste xenon. The gas trap leakage is included in the 25% overall fraction of loss assumed in (5) above. The calculations for effluent to the unrestricted environment are as follows:

$A = 50\ mCi = 5 \times 10^4\ uCi$ max weekly activity

$f = .25$ = total loss

$V_{Total} = V_{Hood} + V_{Fan} = 2.0 \times 10^6\ ft^3/wk + 1.7 \times 10^6\ ft^3/wk = 3.7 \times 10^6\ ft^3/wk$

$\frac{A}{V} \times f = (5.0 \times 10^4\ uCi)\ (.25)/(3.7 \times 10^6\ ft^3)\ (2.832 \times 10^4\ ml/ft^3) = 1.2 \times 10^{-7}\ uCi/ml$

This figure reflects the 168 hr/wk use of the laboratory fume hood and 40 hr/wk use of one of the camera room fans. The actual schedule of operation of the camera room fans will be administratively controlled (SOP attached here as Tab A) so as to provide adequate dilution to assure compliance with 10CFR20.106. As noted in (5.) above, the laboratory hood will run 168 hr/wk.

b. The NONEX gas trap has been subjected to an empirical evaluation by the RPO and the results were compared to the usage chart supplied by the manufacturer. Based on this study, a standard recommendation was made by the RPO for frequency of filter replacement.

In addition, the filter will be re-evaluated at the end of each month (every 10 - 12 studies) by attaching a standard - size plastic bag to the output hose of the filter and counting the collected effluent against background on the gamma camera in Camera Room 4 with the collimator removed. Results will be logged for comparison and analysis by the RPO.

c. Saturated filter elements from the NONEX gas trap will be handled by the Health Physics personnel. They will be stored for decay in the decay cabinet beneath the fume hood in the waste lab, Bldg 603. The nearest unrestricted/occupied area is separated by the 1 inch lead lining of the cabinet and a solid wall (see diagram #7 of Tab A to Item 11, Facilities and Equipment).

Ventilation during occupancy of the waste lab is provided by the fume hood. The ports of the filter element will be tightly capped in order to prevent leakage and its resultant ambient air concentration of Xe-133.

ITEM 21

Standard Operating Procedure: Xenon Studies

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

Nuclear Medicine Service
Standard Operating Policies and Procedures:
Xenon-133 Studies

Routine Procedures

1. Dose will be calibrated in the Nuclear Medicine Laboratory prior to the procedure and will be shielded for transport to the camera room.

2. The patient will be counseled thoroughly prior to dose administration, especially regarding the importance of cooperation and not accidentally releasing the gas.

3. Nose clamps will be used whenever possible, consistent with the welfare of the patient.

4. The camera room fan will be turned on before the machine is loaded and will be run for at least on hour nonstop any time a procedure is performed.

Emergency Procedure

In the event of an accidental release of Xenon in a camera room, the following procedure will be followed:

1. The room will be evacuated by the patient and all personnel.

2. The room will remain vacant with the fan running and door open for at least 30 minutes and will not be unguarded during this time.

3. The RPO (phone 3826) will be notified immediately of the release.

Tab B

ITEM 21

Manual for Xenon Lung Function Unit

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

INSTRUCTION MANUAL

Xenon-133 Lung Function Unit

MODEL 36-001

NUCLEAR ASSOCIATES, INC.
Subsidiary of
RADIATION-MEDICAL PRODUCTS CORP.
100 VOICE ROAD • CARLE PLACE, NEW YORK 11514 • (516) 741-2842

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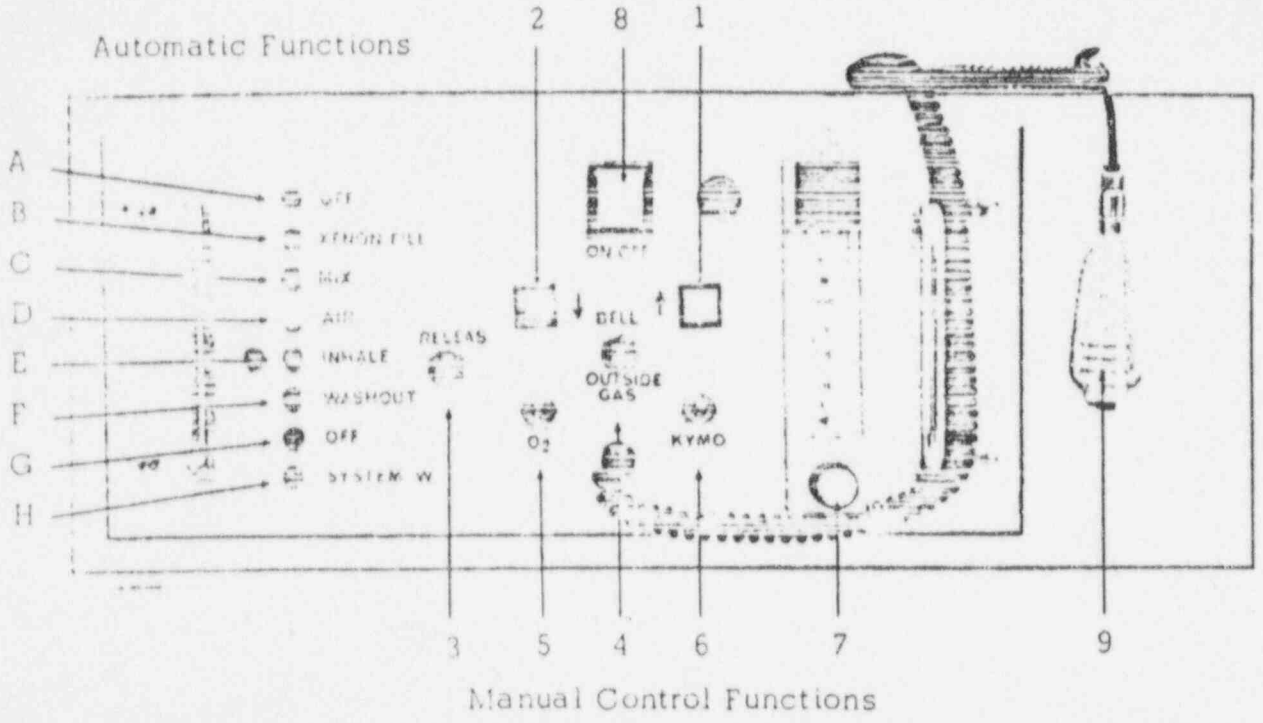
ILLUSTRATIONS

I. INTRODUCTION

The Xenon-133 Lung Function Unit is a fully-automated system for performing pulmonary function studies. It is operated by means of a hand-held remote controller attached to a 10-foot coil cord. The operator indexes the system as desired.

Many modes of operation are possible. The automatic sequential functions provide for single-breath, steady state and washout analyses. The unit provides a homogeneous gas mixture for the patient and resistance-free breathing in both patient equilibrium and washout modes. The unit will accept an internal or external xenon (tank or gun) supply and an internally mounted O_2 bottle and regulator. The patient mouthpiece is mounted on a fully-shielded arm which is vertically adjustable from 40" to 50" above floor level. The device is cart-mounted with 5" casters and locks.

Fig. 1 Front Panel



II. AUTOMATIC FUNCTIONS

The automatic functions are indexed by a remote hand switch and are in the following sequence (see left side of Fig. 1):

A. OFF -- Top light indicates that unit is off. The unit is placed in this mode prior to administration of xenon gas.

B. XENON FILL -- Xenon is filled from an internal cylinder, external cylinder, or xenon gun. The unit can accept an internal or xenon tank through the side door. An external cylinder can be attached to the external gas port, and gas can be added while depressing the "Outside Gas" switch. (See Fig. 1).

C. MIX CYCLE -- Gas in the system is mixed by an internal blower. The blower will provide a homogeneous mixture in the spirometer and associated tubing within a running time of two minutes.

D. PATIENT AIR -- The patient is positioned and breathes ambient air (through system) to adjust to the mouthpiece and system. External air is drawn through the external air inlet (located on the underside of the adjustable arm, Fig. 4) and delivered to the patient. The patient exhales through the washout system to adjust to the unit.

E. INHALE -- Manually initiated as the patient exhales completely. Upon inhalation, the system automatically places the patient in the closed-circuit spirometer system. A second indicator light signals the technician to start time/count data acquisition, and the 3-speed kymograph is automatically switched on. The system maintains this steady-state condition until the operator moves to the washout cycle. Oxygen is fed into the system from an internally-mounted bottle and is regulated to maintain sufficient oxygen supply to the patient. An internally-mounted, removable CO_2 soda lime absorber is included in the system to remove exhaled CO_2.

F. PATIENT WASHOUT -- Patient inhales external air and washes out through the system. When the camera indicates that the patient is sufficiently free of xenon, the operator moves to the "OFF" position. The gas volume left in the spirometer is trapped and can be re-used by indexing the system back to the "PATIENT AIR" mode.

G. OFF -- Patient is removed from the system. Upon completion of patient washout, the system is totally sealed.

H. SYSTEM WASHOUT -- An internal blower flushes the entire system rapidly and guarantees that no residual xenon-133 remains. The effluent gas is discharged through the external gas port located at the lower left rear of the cabinet. The supplied discharge hose is attached to this port and vented through a window or an exhaust hood. The unit will eliminate all internal gas in approximately five (5) minutes.

The system is now indexed back to "OFF" (Step "A") and is ready for the next study. Sequential functions can be overridden at any time by means of the remote controller. The patient can become acclimated to the system (before the analysis begins) by breathing ambient air through the system.

III. MANUAL CONTROL FUNCTIONS

See center of Figure 1 for location of controls.

1. RAISE BELL -- Fills the system with air via pump. Momentary switch operation.

2. LOWER BELL -- Adjust bell volume to clinician's requirements. Momentary switch operation.

3. BELL OVER-FILL RELEASE -- Releases bell and places unit automatically in washout mode.

4. EXTERNAL GAS INLET -- Used to charge the system with xenon from an external source or to admit [illegible]izing agent (i.e., ethylene oxide).

5. O_2 "ON" SWITCH -- Allows O_2 to flow to rotameter (7)

6. KYMOGRAPH -- MANUAL ON-OFF SWITCH -- For use in other than automatic mode.

7. OXYGEN REGULATOR & FLOW VALVE -- Provides O_2 replenishment (or O_2 fill) to spirometer system. Precision flowmeter (with needle valve) regulates O_2 supply.

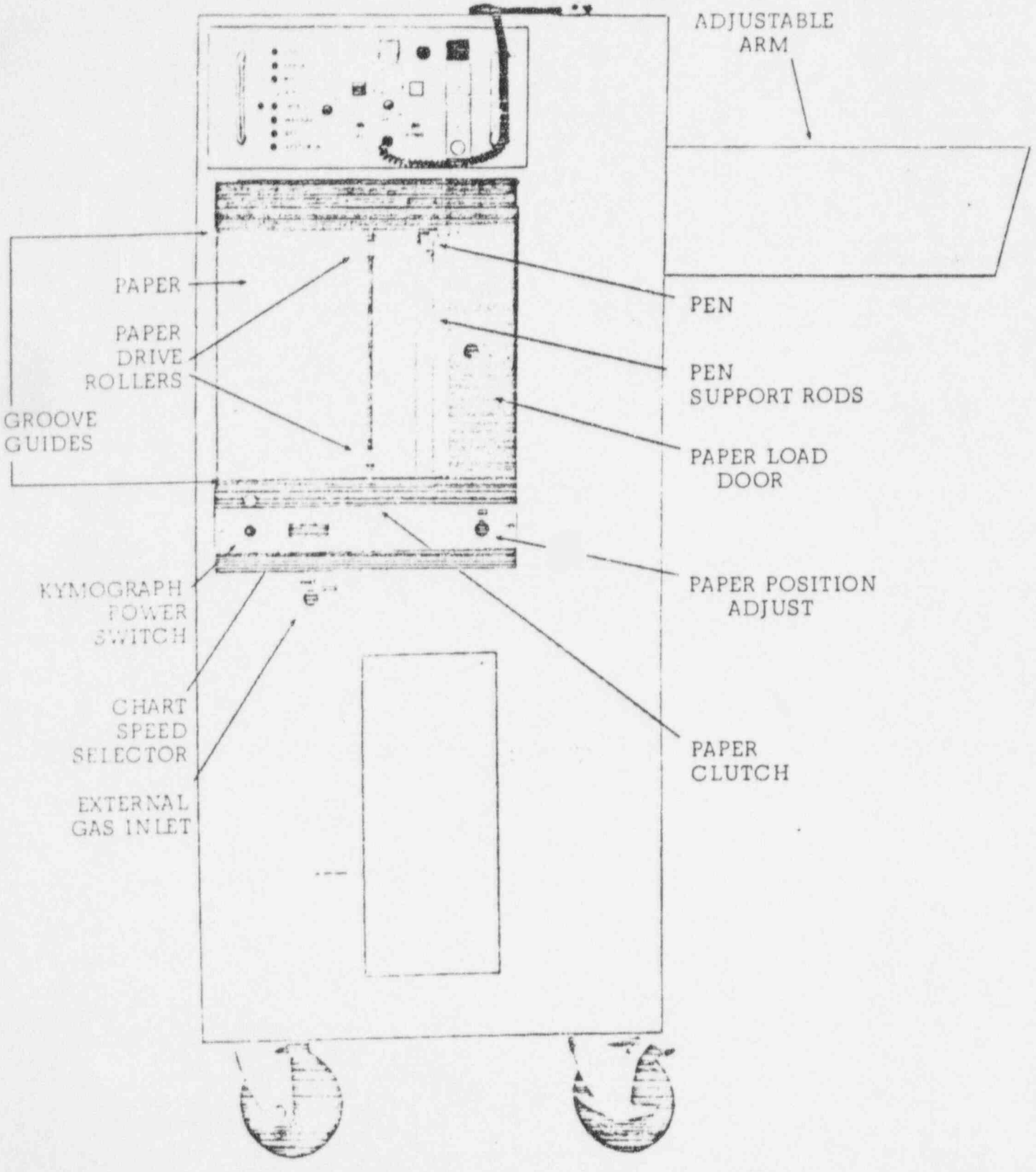
8. ON-OFF SWITCH

9. HAND-CONTROLLER - For indexing system to each cycle.

AUTO SHUT-OFF -- Turns off the system (in case of bell over-fill) and actuates an audible alarm.

FILL CAP -- For adding xenon into the system with a xenon gun or syringe. Located on the shielded arm behind the shielded port. Serum cap allows injection of xenon-133 as a bolus or for a nomogeneous mixture.

Fig. 2. Front View



IV. INSTALLATION INSTRUCTIONS.

1) Carefully remove all packing material.

2) While facing the front of the instrument, open the small access door located on the right side panel. Release the adjustable arm counterweight by loosening the round-head screw located on the left inside wall below the access door level. Back the screw out at least 10 turns. Move the arm to its upper and lower travel limits to insure that it has been freed. (Fig. 4)

3) Fill the soda lime absorber (Fig. 4) by unscrewing the top (section with "L" fitting). Make sure that the soda lime used is dust free. Carefully pour the soda lime into the housing until it is one-third full. Tap gently and repeat until the canister is full.

4) Replace the top and install into the unit through the right-side access door. Place the section with the straight fitting into its rubber receptacle located opposite the lower part of the access door. Then insert the "L" fitting into its mating sleeve. Make sure that the absorber is fully seated. Close the side access door.

5) Open the rear door and examine all tube connections. Make sure that they are properly seated. If any tubing is dislodged, ascertain its correct location with the flow diagram. (Fig. 3 and 7)

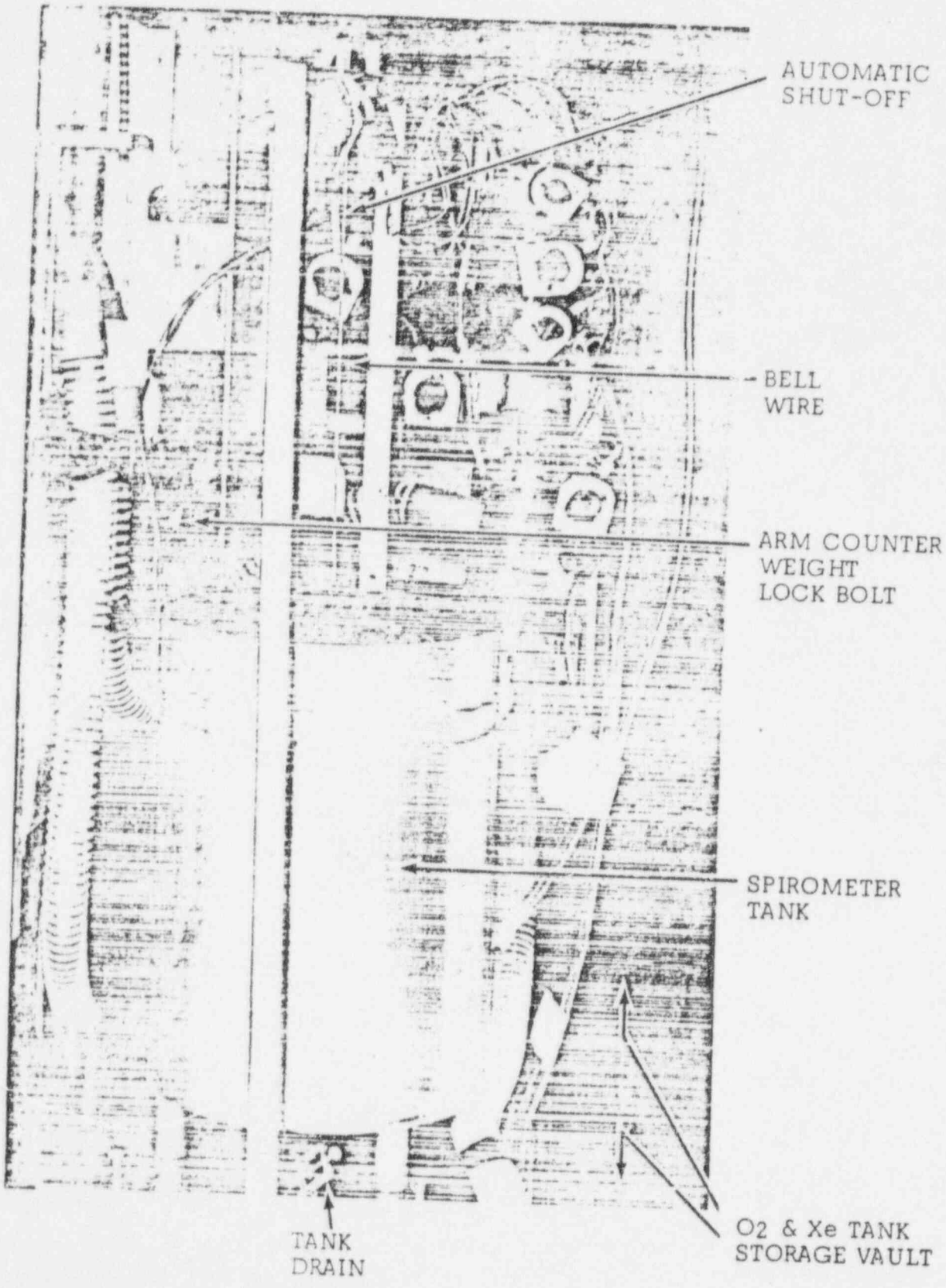
6) Free the spirometer bell carefully. Free the bell wire taped to the upper support arm, and pass it over the bell pulley located at the end of the arm.

7) Secure the bell wire to the bell clip. Manually raise and lower the bell to insure that no binding occurs. DO NOT USE FORCE. If binding occurs, remove the front panel by means of the four (4) panel screws. Carefully slide out the front control panel one-third of the way. On the right side of this cavity the bell wire passes over a pulley, changing its direction (down) and allowing it to drive the kymograph pen. Make sure that the wire is on the pulley. If not, carefully lift the wire onto the grooved pulley. The system will now move freely. Replace the front panel carefully. (Fig. 3)

8) Fill the spirometer tank with DISTILLED WATER to the FILL line indicated on the tank. Before doing this, make sure that the spirometer tank drain is closed. This is located at the end of a plastic tube inserted on the underside of the tank. Grasp the tubing and slide it out. A standard hose clamp is located at the end of this tubing. Make sure that it is closed. Replace the tube back under the tank.

Note: You may choose to add a small amount of a free iodine radical to the tank water to maintain sterility. The spirometer tank water should be changed at one month intervals.

Fig. 3 Spirometer & Valves



9) Open the left-side access door and the rear access door. Carefully place the xenon tank/regulator system through the side door. Place the O_2 cylinder (with regulator) into the storage slot through the rear door. Carefully connect the appropriately labeled hoses to their respective cylinders. Make sure that an adequate seal is made. (Fig. 3)

10) Adjust the O_2 regulator to a maximum pressure of 4 pounds per sq. in. (PSIG). Do not turn the xenon regulator on. Close the access door.

11) To load the paper into the kymograph, open the flap door on the right side of the recorder. Insert the paper (top first) and push up. Then insert the lower half of the roll into its receptacle. Close the flap door. (Fig. 2)

12) Thread the paper under the pen support rods, through the groove guides located at the top and bottom of the kymograph, and under the drive rollers. Make sure that the drive rollers are declutched by moving the drive clutch lever to the "off" (left) position. Feed the paper through the cut-off slot located on the left side of the kymograph.

13) Install the pen through the hole on the pen carriage. This counterweighted holder will contact the paper with the pen installed. Engage the drive system by moving the clutch Control to the right. Turn the kymograph switch on. Move the manual kymograph switch on the control panel to the "on" position. Check all three speeds (30, 60, 1200 mm/min.). The pen should draw a clear bold line. Turn the manual kymograph switch on the control panel to "off".

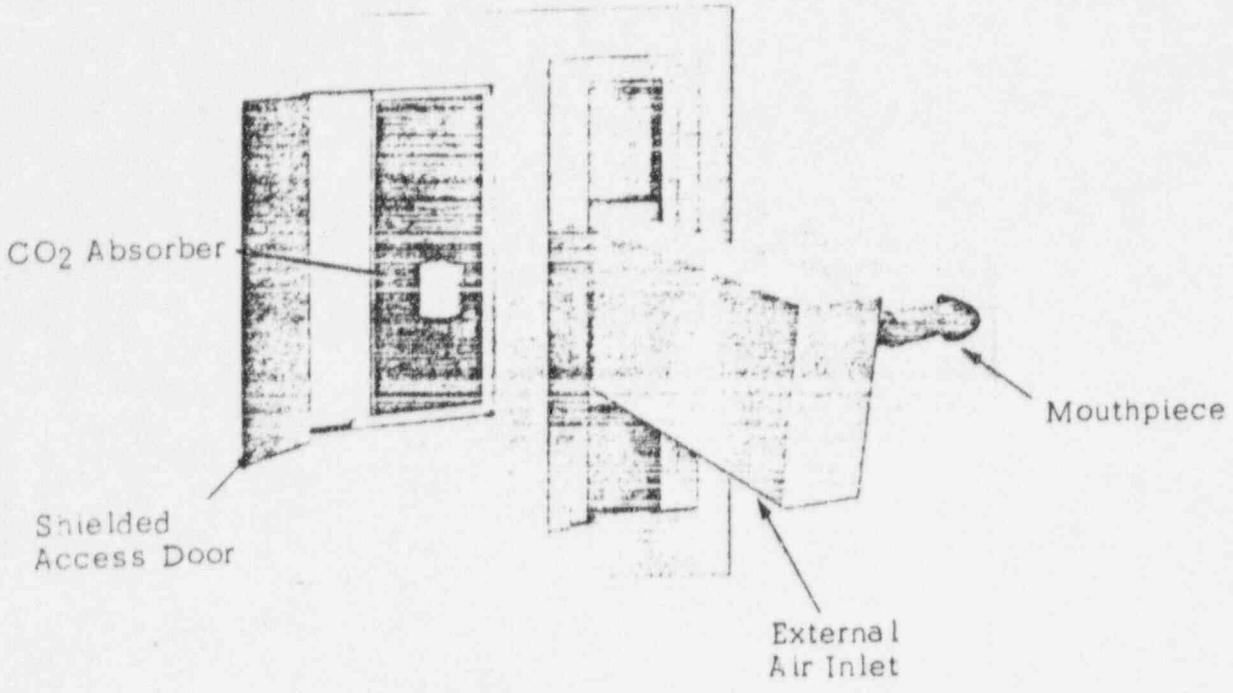
14) Advance the system through all modes with the hand controller.

15) Fill the bell until the overfill alarm activates. Observe the bell to be sure it is not above the water level. If it is, adjust the microswitch. If insufficient H_2O is in the spirometer, fill to the proper level. (Fig. 3)

16) Test the bell overfill release. The bell should drain and stop upon release of the switch.

17) Proceed to "Operating Instructions."

Fig. 4 Side View



V. OPERATING INSTRUCTIONS

1. Turn the unit on by depressing the momentary on/off switch (Fig. 1, #8).

2. Using the remote hand control (Fig. 1, #9), advance the system staging to the OFF position (top light).

3. Open the left side and rear doors and examine both the O_2 and Xe tanks in the following manner:

   A. Oxygen Tank

      1) Make sure that the gas fittings are properly installed and that the O_2 tank main valve is closed. (Using the wrench supplied, the valve should be fully clockwise.)

      2) Go to the front panel of the instrument and place the O_2 switch in the ON (up) position. Return to the left side access door. Crank the O_2 regulator valve fully counter-clockwise and open the main valve with the wrench.

      3) Open the valve on the O_2 regulator. Turn counter-clockwise from the OFF position. Advance the O_2 regulator valve clockwise until a flow rate of 100 cc per minute is displayed by the flowmeter ball indicator. Remove the wrench from the valve and close the O_2 flowmeter valve by turning fully counter-clockwise. Turn the O_2 switch to OFF. (Fig. 1)

B. Xenon Tank & Standard Operating Instructions

1) Make sure that all gas fittings are properly in place.

2) The xenon tank main valve should be fully closed (clockwise) and the xenon regulator OFF.

3) Using the hand controller, advance the system sequencer to the "Xe fill" position.

4) Using the wrench supplied, open the main Xe valve (right).

5) On the front panel. depress the square "Bell Down" switch (1) until the kymograph pen is at the top of its travel. (In effect, the bell is completely empty and the indicator pen rests at the highest point on the chart.)

6) Depress the square "Bell Up" switch (2) until the volume displayed by the kymograph pen is at 1 liter.

7) Consulting the data supplied by the xenon gas supplier, determine the concentration of Xe-133 gas per liter in the tank. Correct the concentration for decay, using the table supplied.

8) It has now been determined what volume of gas is required to be added to the system to have the correct quantity ^{133}Xe present.

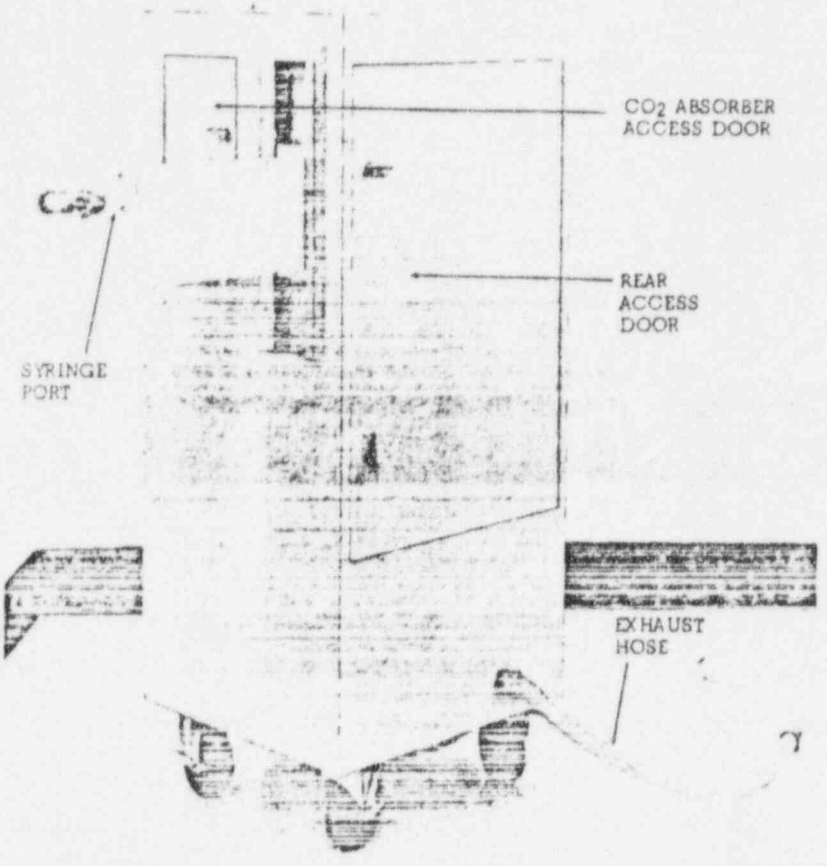
9) Observing the kymograph pen and holding the hand controller, slowly turn the Xe regulator control valve clockwise until the kymograph pen indicates that the correct volume of Xe gas has been added to the spirometer. Advance the system, using the hand controller, to the MIX cycle (c). This automatically terminates the flow of Xe into the spirometer valve. Turn the Xe regulator valve OFF (counter-clockwise).

10) Using the square "Bell UP" momentary switch (2), add an appropriate amount of air to the spirometer bell. (Bring the kymograph pen to the 6-liter line.) Allow the system to MIX the Xe-air components for 2 minutes.

11) Using an appropriate Xe source, set the camera isotope peak to the correct value.

12) Place the patient on the system. Advance the system to "AIR" (d), using the remote hand control (9). Install the nose clip on the patient and look for any breathing difficulty. If the patient's condition indicates that he is not having breathing difficulty, proceed. As the patient is

Fig. 5 Rear View



exhaling, index the system to the INHALE cycle (E) using the remote hand control. When the second INHALE light goes on and the audible sound of the air control solenoid can be heard, start the camera count. Be sure the patient holds his breath for a sufficient time. Upon exhalation of the first static shot, turn the O_2 switch (5) on. Observe the kymograph display, noting the slope of the inspiration/expiration readout. If the slope is excessively high, adjust the O_2 flow rate accordingly to replace the lost O_2 volume (150 cc/min. is usually sufficient).

After equilibrium is attained by the patient, advance the system (using remote hand control) to PATIENT WASHOUT (F). Turn the O_2 switch off. Make sure that the patient is sufficiently clear of xenon (using camera count/rate) before removing him from the system. When the patient has washed out, advance the unit to the OFF (G) position and remove the patient.

Advance to SYSTEM WASHOUT (H) and allow to flush for 5 to 10 minutes. You may wish to add a sterilizing agent to the system at this point, utilizing the external gas fill switch (4) located on the front panel. After the system washout is complete, advance the system to the OFF position. Turn the unit off. Turn the O_2 regulator off. Turn the main O_2 valve OFF, using the wrench. Turn the xenon valve off.

C. Xenon Syringe/Gun

Repeat "B" but administer xenon through syringe on "Mix" for homogenous mixture or on "Inhale" for a bolus thru the injection port located on the arm.

VI. GENERAL PARTS LIST

Quantity	Description
1	1" D Solenoid Valve
1	3/4" D " "
1	1/2" D " "
1	1/4" D " "
1	Breathing Valve
1	Bisquit Blower (Breathing Circuit)
1	" " (Exhaust Circuit)
1	Air Pump (Pickoff Circuit)
1	Pressure Transducer/Switch
1	1" D Reinforced Tube - 18" long
1	1" D Reinforced Tube - 22" long
1	1" D Reinforced Tube - 25" long
1	1" D Reinforced Tube - 34" long
1	Stepping Switch 4 Decks 10 Contacts/Deck
2	DPDT Momentary Switch
2	SPDT Momentary Switch
1	DPDT Illuminated Switch
1	SPST Toggle Switch
9	Mural Indicator Lights
1	DPDT Relay (Guardian)
1	Microswitch (Bell Overfill)
1	Transformer
1	Bridge Rectifier
1	Alarm Buzzer
4	Jones Plugs (Mated pairs)
1	1/4" ID Nalgene "T" Connector
1	Feed-thru Connector 5/32" to 3/4" ID
1	Feed-thru Connector 5/32" ID

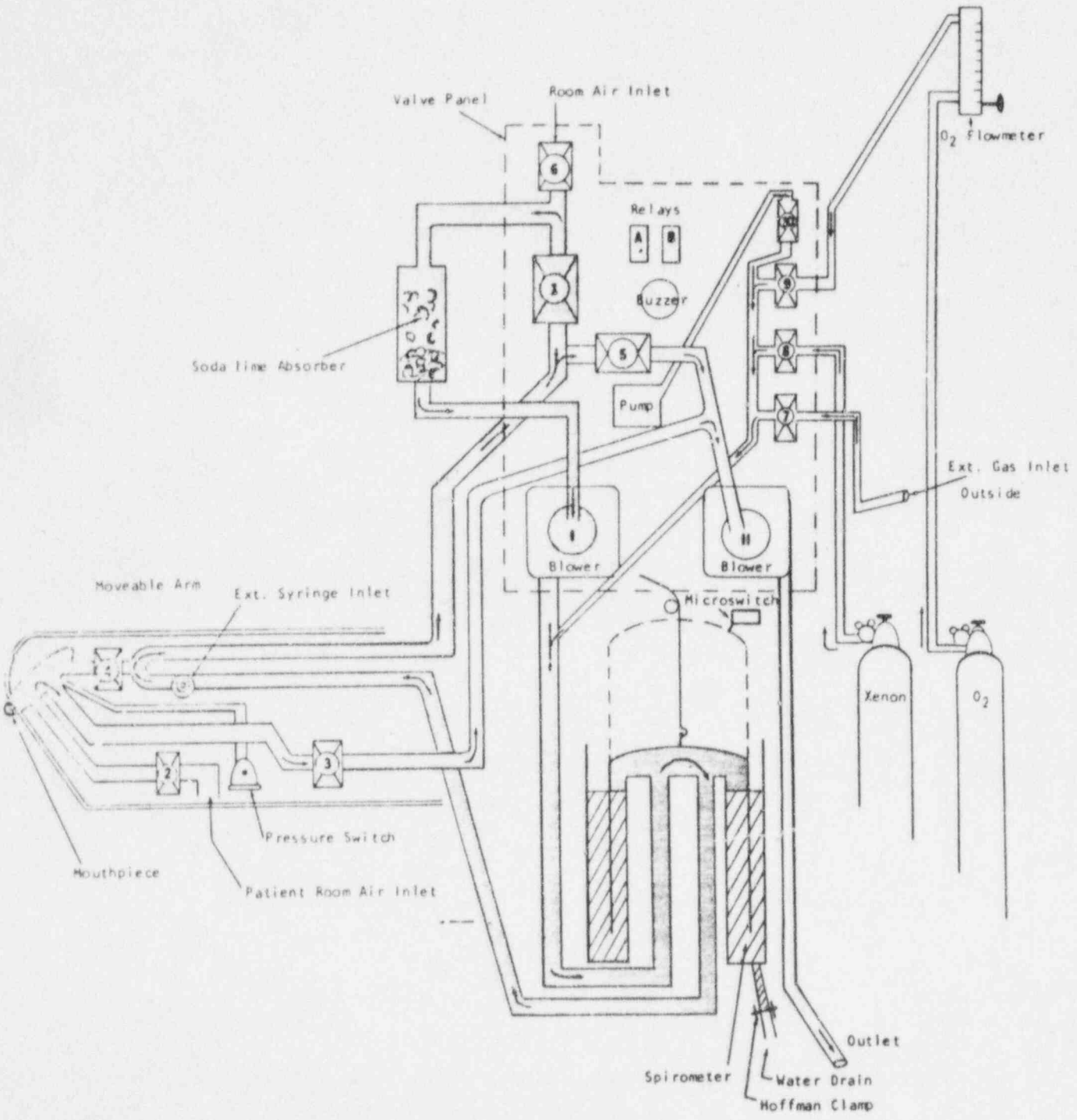
Fig. 6 Wiring Code

Function/Mode \ Component Wiring Code	Light Indicator	Valve #1 - yellow	Valve #2 - red	Valve #3 - red	Valve #4 - white/green	Valve #5 - grey	Valve #6 - orange	Valve #7 - blue	Valve #8 - white/brown	Valve #9 - purple	Valve #10 - white/orange	Blower #1 - yellow	Blower #2 - brown	Air Pump - white/orange	Kymograph - white/red	Pressure Sens. Switch - blue	Overfill Micro Switch - white/black	Relief Relays A & B - white/blue	Alarm Buzzer - red
1 Off	1																		
2 Xenon Fill	2	x							x			x							
3 Mix	3	x										x							
4 Patient Air	4	x	x	x								x	x						
5 Inhale	5	x	x	x								x	x						
6 Inhale (Xenon)	5	x			x							x			x				
7 Washout	6		x	x									x						
8 Off	7																		
9 System Washout	8					x	x						x						
Ext. Gas Inlet Relay	*M/S							x											
Syringe Gas Inlet																			
Oxygen										x									
Raise Bell	*M/S										x			x					
Lower Bell	*M/S					x							x						
Kymograph															x				
Overfill Shut-off																	x		x
Overfill Release	*M/S																	x	

*M/S -Momentary Switch

Fig. 7

Flow Chart Schematic



Equilibrium Cycle

ITEM 22

Procedures and Precautions for Use of Radioactive Materials in Animals

22. Animal uses of radioactivity at FAMC are currently being done in Clinical Investigation Service.

a. Animals will not be housed as such after receiving internal doses of radioactive materials under the current provisions of the license. Animals which receive injections of radioactive material will be kept in a controlled area designated for radioisotope use. They will be kept in containers which can be decontaminated and will be sacrificed for experimental purposes within several hours after injection

b. Instructions to animal caretakers are included here as an SOP, Tab A.

C. See Tab A.

d. Since experimental animals are retained in controlled radioisotope use areas as described above, they will at all times after dose administration

(1) be under the direct administrative control of the radioisotope user, or

(2) be in a restricted access area with doors locked.

ITEM 22

Instructions to Animal Caretakers

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

Standard Operating Procedure

Instructions to Caretakers of Animals
Containing Radioactive Materials: Clinical Investigation Service

1. The following procedures shall apply to animals which receive internal doses of radioactive material in the course of experiments in the Clinical Investigation Service.

a. Animals

(1) Potentially contaminated animal excreta will be treated as contaminated waste unless surveyed by the caretaker and proven otherwise.

(2) Contaminated animal carcasses and excreta will be disposed of in accordance with FAMC Reg 40-604 and the instructions of the RPO; no disposal will be made without consulting the RPO.

b. Facilities

(1) Facilities occupied by such animals will be surveyed at the end of each experimental protocol, to include swipe testing for removable contamination.

(2) If removable contamination is found, standard decontamination procedures will be followed by the radioisotope user and the area will be checked again with swipe tests.

(3) The RPO will be provided with copies of all swipe test results, to include ones which are initially negative for contamination.

ITEM 23

FAMC Bioassay Program

Renewal Application for FAMC NRC License
05-00046-13
26 February 1979

Fitzsimons Army Medical Center

Bioassay Program

The FAMC Bioassay Program is a comprehensive institutional program under the direction of the Radiation Protection Officer and Health Physics Section. Control at the institutional level is vested in the Radioisotope Committee, which recommends bioassays for any procedures which are likely to cause internal exposures to personnel.

In addition, the Radiation Protection Officer has reviewed the entire program at FAMC and has identified three current areas of concern:

a. Preparation of Therapeutic Doses of I-131. Personnel in the Nuclear Medicine Service who handle millicurie amounts of I-131 or I-123 will receive thyroid uptake measurements in Nuclear Medicine Service within 72 hours of exposure. Action levels and other guidelines will be those in NRC Regulatory Guide 8.20.

b. Iodination Procedures: Personnel in Clinical Investigation Service who perform bulk labelling of compounds with I-125 will receive thyroid uptake measurements from Nuclear Medicine Service exactly as described in paragraph (a) above.

c. Tritium: Any personnel in Clinical Investigation Service who handle more that 10 mCi of tritium at any time will receive urine bioassay in accordance with Appendix D of AR 40-37, which currently states the following:

In the case of uncontained tritium labeled organic compounds, urinalysis by liquid scintillation counting will be effected weekly whenever the amount used in a single procedure is greater than 10 millicuries. Any urinalysis revealing in excess of 25 microcuries/liter in a 24-hour urine collection will result in the individual being removed from duties involving tritium exposure until the urine concentration has dropped to 5 microcuries/liter, as revealed by subsequent liquid scintillation tests.

Any further bioassay requirements that may be determined by FAMC Radioisotope Committee will be appended to this program statement.