DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, D.C. 20315

IN REPLY REFER TO:
MEDPS-PE

28 June 1966

Isotopes Branch
Division of Materials Licensing
U. S. Atomic Energy Commission
Washington, D. C. 20545

Gentlemen:

Recommend approval of the inclosed application for renewal and amendment to Byproduct Material License No. 5-46-13 for Fitzsimons General Hospital, Denver, Colorado.

Sincerely,

C. R. LEWIS, JR.
Colonel, MSC
Preventive Medicine Division

1 Incl
as (in trip)

A/27

FITZSIMONS GENERAL HOSPITAL
U. S. ARMY
DENVER~~30~~, COLORADO 80240

IN REPLY REFER TO
MEDEO

23 June 1966

SUBJECT: Application for Renewal and Amendment to AEC Byproduct Material License No. 5-46-13 (A66)

THRU: Commanding General
U. S. Army Medical Research and Development Command
Office of The Surgeon General
ATTN: Chief, Medical Research Branch
Department of the Army
Washington, D. C. 20315

TO: The Surgeon General
ATTN: MEDPS-PO
Department of the Army
Washington, D. C. 20315

Submitted herewith is application for renewal and amendment to Byproduct Material License No. 5-46-13(A66), AEC Form 313, and appendices A through H in six copies for appropriate processing.

1 Incl
as

ROBERT E. BLOUNT
Major General, MC
Commanding

ADDRESS ALL COMMUNICATIONS TO THE COMMANDING GENERAL
FITZSIMONS GENERAL HOSPITAL

Form AEC-313 (5-58)

ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved. Budget Bureau No. 38-R027.4

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application. If application is for renewal of a license, complete only Items 1 through 7 and indicate new information or changes in the program as requested in Items 8 through 15. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail three copies to: U. S. Atomic Energy Commission, Washington 25, D. C. Attention: Isotopes Branch, Division of Licensing and Regulation. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material 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, Part 20.

1. (a) NAME AND STREET ADDRESS OF APPLICANT. *(Institution, firm, hospital, partnership, etc.)*

Department of the Army
Fitzsimons General Hospital and
US Army Medical Rsch & Nutrition Lab
Denver, Colorado 80240

(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. *(If different from 1 (a).)*

Same as Item 1(a) and
Summit of Pikes Peak, Colorado
(See 6(a), QQ to WW)

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Radiology Service
USAMRNL

3. PREVIOUS LICENSE NUMBER(S). *(If this is an application for renewal of a license, please indicate and give number.)*

5-46-13(A66) Renewal and Amendment
(Also 5-46-9, 5-46-10, 5-46-11, 5-46-12)

4. INDIVIDUAL USER(S). *(Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)*

Users approved by the Radioisotope Committee.
(See Appendix A for list of Radioisotope Committee members. See Appendix B for copies of AEC-313a for ind. approved for human use.

5. RADIATION PROTECTION OFFICER *(Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)*

As designated by Radioisotope Committee (Maj David F. Preston, MC. See Appendix B for training and experience)

6. (a) BYPRODUCT MATERIAL *(Elements and mass number of each)*	(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. *(If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.)*	
A. Iodine 131	A. Iodide	A. 250 millicuries
B. Iodine 131	B. Iodinated Human Serum Albumin	B. 5 Millicuries
C. Iodine 131	C. Hippuran	C. 2 millicuries
D. Iodine 131	D. Rose Bengal	D. 2 millicuries
E. Iodine 131	E. Triolein and/or Oleic Acid	E. 2 millicuries
F. Iodine 131	F. Chologratin	F. 2 millicuries
G. Iodine 131	G. p-Toluidine Polyvinylpyrrolidone	G. 2 millicuries
H. Iodine 131	H. Thyroxine	H. 2 millicuries
I. Iodine 125	I. Iodide	I. 1 millicurie
J. Iodine 125	J. Iodinated Human Serum Albumin	J. 1 millicurie
K. Iodine 125	K. Hippuran	K. 1 millicurie
L. Iodine 125	L. Rose Bengal	L. 1 millicurie
See Appendix C	See Appendix C	

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. *(If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)*

Sections A through EE have been documented previously in application dated 6 Dec 63 for AEC Byproduct Material License No. 5-46-13(A66).

Sections FF through PP have been documented previously in Inclosure entitled "Request for approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" attached to application for amendment to AEC Byproduct Material License 5-46-13(A66) dated 12 March 1964.

Sections QQ through SS have been documented in applications for amendment to AEC Byproduct Material License 5-46-13(A66) dated 12 Aug 64 and dated received 4 Jun 65.

Sections TT through WW are documented in Appendix G attached.

See Appendix D

(Continued on reverse side)

APPENDIX A 21 Jun 1966

The Radioisotope Committee of Fitzsimons General Hospital and U. S. Army Medical Research and Nutrition Laboratory is composed of the following members:

Col. John W. White (167)
~~Colonel David E. Thomas~~, MC, Chief, Department of Surgery
Colonel Edwin A. Overholt, MC, Chief, Department of Medicine
Lt Colonel Paul E. Siebert, MC, Chief, Radiology Service
Lt Colonel Paul W. Palmer, MC, Chief, Department of Pathology
Lt Colonel John E. Canham, MC, Commanding Officer, USAMRNL
Major David F. Preston, MC, Chief, Radioisotope Section, Radiology Service
Captain Charles G. Liddle, VC, Chief, Radioisotope Section, Physiology Division, USAMRNL

Major David F. Preston is Radiological Safety Officer, and Lt Colonel Paul E. Siebert is Chairman of the Radioisotope Committee.

The experience with radioisotopes for Major David F. Preston, Lt Colonel Paul E. Siebert and Lt Colonel John E. Canham is attached to their Form AEC-313a. The training and experience for Captain Charles G. Liddle is attached.

These members are the only members of the Radioisotope Committee who have had experience with radioisotopes. The Chief, Department of Surgery, Chief, Department of Medicine and the Chief, Department of Pathology are members of the Radioisotope Committee as required by paragraph 3d, AR 40-37.

Form AEC-313a (11/63) 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. Back of page may be used for comments.

9. NAME AND ADDRESS OF APPLICANT PHYSICIAN

DAVID T. PRESTON, MAJOR, MC, USA

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 9 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)
	Hippuran - Diag. of Renal Function		395
I-131	Diagnosis of thyroid function		2008
	Dilution studies		388
	Excretion studies		138
	~~Brain tumor localization~~ Placental Localization		9
	Scanning studies		824
	Treatment of hyperthyroidism		92
	Treatment of cardiac conditions		2
	Treatment of thyroid carcinoma		18
P-32 Soluble	Treatment of polycythemia		2
	Treatment of leukemia		14
	Treatment of bone metastases		1
	Tumor localization		--
	Intracavitary treatment		--
	Interstitial treatment		--
Au-198	Intracavitary treatment		--
	Interstitial treatment		--
	Scanning studies		106
Cr-51	Blood determinations		58
	Scanning studies		1
~~Co-58 or~~ Co-60	Diagnosis of pernicious anemia		50
Co-60	Interstitial treatment		--
I-192	Intracavitary treatment		--
Co-60 or Cs-137	Teletherapy treatment		--
	Treatment of superficial diseases of the eye		--
Sr-90			337
Other Isotopes Use back of page	Hg-197 Scanning Studies		69
	I-203 Scanning Studies		24
	Fe-59 Iron Turnover Studies		

Key to Column (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.

11. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING Sep '62 - Feb '63 Aug '63 - Jul '65 4800 hrs

is certified by the Radioisotope Committee

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE ~~WAS OBTAINED UNDER THE SUPERVISION OF~~

US Army Tripler General Hospital
APO San Francisco, Calif. 96438 03-450-4

JAMES A. GARRISON
Colonel, MC, USA
President, Radioisotope Committee

AT (Institution) Name and Address (Byproduct Material License Number) (Signature of Preceptor)

4 January 1966

TRAINING AND EXPERIENCE RELATING TO RADIOISOTOPES OF DAVID F. PRESTON, MAJOR, MC, 09'669

University of Cincinnati - BS Physics 1955.
General Physics - lecture and laboratory, 2 semesters.
Electricity and Magnetism lectures and lab, one semester.
Modern Atomic Physics lecture and lab, 2 semesters.
Calculus - 2 semesters.
Differential Equations, one semester.
Advanced Calculus, one semester.

University of Cincinnati College of Medicine, MD 1959.
Intern, Walter Reed General Hospital, July 59-June 60.
Resident, Internal Medicine, Sept. 60-Aug 63.
Training at Tripler Isotope Clinic, 9 months.
Chief, Radioisotope Clinic, Aug 63-July 65, Tripler General Hospital.

DAVID F. PRESTON
Major, MC
Chief, Radioisotope Section

Form AEC-313 a (3-56) Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38-R010.1

This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9. (a) USING PHYSICIAN'S NAME	(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a))
PAUL E. SIEBERT, Major MC Fitzsimons General Hospital	Denver 40, Colorado

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN D (circle applicable numbers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function	161	(1) (2) (3) (4)
	Treatment of hyperthyroidism	9	(1) (2) (3) (4)
	Treatment of thyroid cancer	9	(1) (2) (3) (4)
	Treatment of cardiac conditions	1	(1) (2) (3) (4)
	Brain tumor localization		1 2 3 4
	Blood determinations	22	(1) (2) (3) (4)
	Others:		1 2 3 4
			1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia	9	(1) (2) (3) (4)
	Brain tumor localization		1 2 3 4
	Treatment of bone metastases		1 2 3 4
	Others: Eye Tumor Localization	2	(1) (2) (3) 4
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer	3	(1) (2) (3) (4)
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations	7	(1) (2) (3) (4)
	Others:		1 2 3 4
			1 2 3 4
Other Isotopes	Strontium 90	100	(1) (2) (3) (4)
	Cobalt 60 Schilling Test	23	(1) (2) (3) (4)
			1 2 3 4

Key to above numbers (column D) Active Participation and Discussion

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period including reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

70301

11. TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING 480 hours

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF

H. F. Hurd, M. C.

Col. John A. Isherwood, M.C. AT Brooke General Hospital, Fort Sam Houston, Texas

(Name of physician (preceptor)) (Institution) (Signature)

Form AEC 313 a (10-61) Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R080.1

This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9. (a) USING PHYSICIAN'S NAME

John E. Canham MC

(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a))

Chief, Metabolic Division
U.S. ARMY Medical Research and Nutrition Laboratory
Fitzsimons General Hospital, Denver, Colorado 80240

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN B (circle applicable numbers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function	20-25	(1) 2 3 4
	Treatment of hyperthyroidism		1 2 3 4
	Treatment of thyroid cancer		1 2 3 4
	Treatment of cardiac conditions		1 2 3 4
	Brain tumor localization		1 2 3 4
	Blood determinations		1 2 3 4
	Kidney function		1 2 3 4
	Others:		1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia	2	(1) 2 3 4
	Brain tumor localization		1 2 3 4
	Treatment of bone metastases		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Other Isotopes			1 2 3 4
	Co^{60} and Vitamin B^{12}	24	(1) (2) 3 (4)
			1 2 3 4

Key to above numbers (column D)

Active Participation and Discussion in the:

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period including reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

11. TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING _____ hours

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF

Dr. John Coniglio PhD Vanderbilt University
Dr. Richard Bozian School of Medicine
Dr. Schneider (Preceptor)) AT U.S.A. Med. Res. & Nut. Lab. (Signature)

Form AEC-313 (5-58) Page Two

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	U.S.Army Hosp. Wurzburg & Ft.San Vanderbilt Univ. School of Med.	2½ yrs 13½ mo	yes no	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Vandererbilt University School of Medicine	4½ mo formal 9 mo on job	Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Same as b. above		Yes No	Yes No
d. Biological effects of radiation	Same as b. above		Yes No	Yes No

9. 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}	0.5uc/patient or subject	Nutrition Clinic, Vanderbilt University.	9 months	Studies on Vitamin B_{12} requirements & half life in humans.
Co^{60}		Dept. Biochemistry Vanderbilt University.	4 months	Relationship B_{12} to Calcium in B_{12} absorpt
C-14, Cr-61, I-131 P-32, H3, K-42		" " "	4 months	Laboratory experience

10. RADIATION DETECTION INSTRUMENTS (Use supplemental sheets if necessary)

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. (For film badges, specify method of calibrating and processing, or name of supplier.)

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) Yes No

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

John E. Canham MC
Applicant named in item 1

Date _____ By: _____

Title of certifying official

WARNING.—18 U. S. C., Section 1001; Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

U.S. GOVERNMENT PRINTING OFFICE: 1961 O—615365

Form AEC-313

Training and Experience: Charles G. Liadle, Capt VC 097002

Item 8 Type of Training:	Where Trained	Duration of Training	
a. Principles and practices of radiation protection	Walter Reed Army Institute of Research	2 weeks	Formal
	Taft Sanitary Engineering Center	4 weeks	Formal
	University of Rochester	1 year	Formal
B. Radioactivity measurement standardization and monitoring techniques and instruments	"	"	"
c. Mathematics and calculations basic to the use and measurement of radioactivity	"	"	"
d. Biological effects of radiation	"	"	"

Item 9 Experience with radiation

Isotope	Maximum amount	Where experience gained	Duration	Type of Use
H^3	1 Mc	Fourth U S Army Med Lab	1 yr	Research
		Walter Reed Army Institute of Research	2 yrs	Research
C^{14}	"	"	"	"
P^{32}	"	"	"	"
S^{35}	"	"	"	"
Ca^{45}	"	"	"	"
Cr^{51}	"	"	"	"
Fe^{59}	"	"	"	"
Co^{60}	"	"	"	"
Zn^{65}	"	"	"	"
Sr^{90}	"	"	"	"
I^{131}	"	"	"	"
Cs^{137}	"	"	"	"
$Ba-La^{140}$	"	"	"	"
Hg^{197}	"	"	"	"
Hg^{203}	"	"	"	"

Form AEC-313 a (10-61) PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R080.1

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1 (a) USING PHYSICIAN'S NAME

David F. Preston, Maj, MC

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a))

U. S. Army Medical Research & Nutrition Laboratory
Fitzsimons General Hospital
Denver, Colorado 80240

2 THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER — (YES) NO

3 A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER — (YES) NO

PROPOSED DIAGNOSIS OR TREATMENT

4 (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary)

A. Iodine 131 — A. Diagnosis of thyroid function and thyroid scanning. Treatment of hyperthyroidism, cardiac conditions and thyroid carcinoma

(See page 2)

(b) CHEMICAL FORM ADMINISTERED

A. Iodide

(See page 2)

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

As described in Appendix to Form AEC-313a submitted as part of application for AEC Byproduct Material License 5-46-13(A66) dated 6 December 1963

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE

(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER — YES (NO)

(2) ON FILE WITH THE ISOTOPES EXTENSION REFER TO APPLICATION NO 5-46-9, 5-46-10, 5-46-11, 5-46-12, 5-46-13 CIRCLE ANSWER — (YES) NO

5 (a) PROPOSED DOSAGE SCHEDULE.—In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary)

As described in Appendix to Form AEC-313a submitted as part of application for AEC Byproduct Material License 5-46-13(A66) dated 6 December 1963

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER — YES (NO)

6 IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES.

Not Applicable

7 THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE CIRCLE ANSWER — (YES) NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8 (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE. Not Applicable CIRCLE ANSWER — YES NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED Not Applicable CIRCLE ANSWER — YES NO

Form AEC-313 a (10-61) Page 2

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A — HUMAN USE

Form approved. Budget Bureau No. 38-R0601

This page may be used for providing additional information. Please cross reference to specific items.

4(a) Con't

B.	Iodine 131	B. Determination of plasma volumes and cardiac output. Cardiac scanning. Localization of brain tumors. Performance of placentograms.
C.	Iodine 131	C. Determination of renal function.
D.	Iodine 131	D. Determination of liver function. Liver scanning.
E.	Iodine 131	E. Determination of fat absorption.
F.	Iodine 131	F. Determination of liver and gallbladder function.
G.	Iodine 131	G. Determination of protein loss. Brain scanning.
H.	Iodine 131	H. Determination of thyroxine turnover.
I.	Iodine 125	I. Diagnosis of Thyroid function and thyroid scanning.
J.	Iodine 125	J. Determination of plasma volumes.
K.	Iodine 125	K. Determination of renal function.
L.	Iodine 125	L. Determination of liver function.
M.	Iodine 125	M. Determination of fat absorption.
N.	Iodine 125	N. Determination of liver and gallbladder function.
O.	Iodine 125	O. Determination of thyroxine turnover.
P.	Phosphorus 32	P. Treatment of polycythemia vera, leukemia, and bone metastases.
Q.	Phosphorus 32	Q. Intracavitary treatment of malignant effusions.
R.	Gold 198	R. Intracavitary treatment of malignant effusions. Insterstitial treatment of prostate carcinoma. Liver scanning.
S.	Chromium 51	S. Determination of red cell mass, red cell survival time, and gastrointestinal bleeding. Spleen scanning.
T.	Cobalt 58	T. Diagnosis of pernicious anemia.
U.	Cobalt 60	U. Diagnosis of pernicious anemia.
V.	Iron 59	V. Determination of iron turnover.
W.	Mercury 197	W. Kidney and brain scanning.
X.	Mercury 203	X. Kidney and brain scanning.
Y.	Hydrogen 3	Y. Determination of total body water.
Z.	Sodium 24	Z. Determination of total exchangeable sodium.
AA.	Selenium 75	AA. Pancreatic scanning.
BB.	Xenon 133	BB. Determination of pulmonary function.
CC.	Strontium 85	CC. Bone scanning.
DD.	Strontium 90	DD. Treatment of superficial eye conditions.

4(b) Con't

B. Iodinated Human Serum Albumin	Q. Colloidal Chromic Phosphate
C. Hippuran	R. Colloidal
D. Rose Bengal	S. Sodium Chromate and/or Chromic Chloride
E. Triolein and/or Oleic Acid	T. Vitamin B12
F. Cholografin	U. Vitamin B12
G. p-Toluidine polyvinylpyrrolidone	V. Ferric Chloride and/or Ferrous Citrate
H. Thyroxine	W. Chlormerodrin
I. Iodide	X. Chlormerodrin
J. Iodinated Human Serum Albumin	Y. Water
K. Hippuran	Z. Sodium Chloride
L. Rose Bengal	AA. Selenomethionine
M. Trolein and/or Oleic Acid	BB. Gas
N. Cholografin	CC. Strontium Nitrate
O. Throxine	DD. Tracerlab Model RA-1 Sealed Medical Applicator
P. Soluble Phosphate	

U.S. GOVERNMENT PRINTING OFFICE 1961 O-611794

Form AEC-313a (11/63) 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. Back of page may be used for comments

9 NAME AND ADDRESS OF APPLICANT PHYSICIAN

DAVID [illegible], [illegible], MC, USA

10 CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 9 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)
	Hippuran - Diag. of Renal Function		395
I-131	Diagnosis of thyroid function		2008
	Dilution studies		358
	Excretion studies		138
	~~Brain tumor localization~~ Placental Localization		9
	Scanning studies		824
	Treatment of hyperthyroidism		92
	Treatment of cardiac conditions		2
	Treatment of thyroid carcinoma		16
P-32 Soluble	Treatment of polycythemia		2
	Treatment of leukemia		14
	Treatment of bone metastases		1
	Tumor localization		--
	Intracavitary treatment		--
	Interstitial treatment		--
Au-198	Intracavitary treatment		--
	Interstitial treatment		--
	Scanning studies		106
Cr-51	Blood determinations		56
	Scanning studies		1
Co-~~58~~ or Co-60	Diagnosis of pernicious anemia		50
Co-60	Interstitial treatment		--
I-192	Intracavitary treatment		--
Co-60 or Cs-137	Teletherapy treatment		--
Sr-90	Treatment of superficial diseases of the eye		--
Other Isotopes Use back of page	Hg-197 [illegible] Studies		337
	[illegible]-203 [illegible] Studies		60
	[illegible] [illegible] Studies		34

Key to Column (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.

11 DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING Sep '62 - Feb '63 Aug '63 - Jul'65 4000 h[illegible]

Is certified by the Radioisotope Committee

12 THE TRAINING AND EXPERIENCE INDICATED ABOVE ~~WAS OBTAINED UNDER THE SUPERVISION OF~~

AT [illegible] General Hospital, San Francisco, [illegible] (Institution) Name and Address

[illegible] (Byproduct Material License Number)

[illegible]
JAMES [illegible]
Colonel, MC, USA
President, Radioisotope Comm[illegible] (Signature of Preceptor)

4 January 1966

QUALIFYING AND EXPERIENCE RELATING TO RADIOISOTOPES OF DAVID P. PRESTON, M.D., M.C., USAFR

University of Cincinnati - BS Physics 1955.
General Physics - lecture and laboratory, 2 semesters.
Electricity and Magnetism lectures and lab, one semester.
Modern Atomic Physics lecture and lab, 2 semesters.
Calculus - 2 semesters.
Differential Equations - one semester.
Advanced Calculus - one semester.

University of Cincinnati College of Medicine, MD 1959.
Intern, Walter Reed General Hospital, July 59-June 60.
Resident, Internal Medicine, Sept. 60-Aug 62.
Rotating at Walter Reed Army Institute, 9 months.
Chief, Radioisotope Section, Walter Reed General Hospital, July 65-

David P. Preston

DAVID P. PRESTON
Major, MC
Chief, Radioisotope Section

Form AEC-313 a (10-61) Page 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R080.1

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME: Paul E. Siebert, Lt Col, MC

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a)): U. S. Army Medical Research & Nutrition Laboratory Fitzsimons General Hospital Denver, Colorado 80240

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER: (YES) NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER: (YES) NO

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary)

A. Iodine 131	A. Diagnosis of thyroid function and thyroid scanning. Treatment of hyperthyroidism, cardiac conditions and thyroid carcinoma.
(See page 2)	

(b) CHEMICAL FORM ADMINISTERED:

A. Iodide
(See page 2)

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

As described in Appendix to Form AEC-313a submitted as part of application for AEC Byproduct Material License 5-46-13(A66) dated 6 December 1963.

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE

(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER: YES (NO)

(2) ON FILE WITH THE ISOTOPES EXTENSION REFER TO APPLICATION NO 5-46-9, 5-46-10, 5-46-11, 5-46-12, 5-46-13 CIRCLE ANSWER: (YES) NO

5. (a) PROPOSED DOSAGE SCHEDULE.—In millicuries for internally administered byproduct material other than discrete fixed sources, and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

As described in Appendix to Form AEC 313a submitted as part of application for AEC Byproduct Material License 5-46-13(A66) dated 6 December 1963.

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER: YES (NO)

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES:

Not Applicable

7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. CIRCLE ANSWER: (YES) NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHEN EVER ADVISABLE. Not Applicable CIRCLE ANSWER: YES NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED. Not Applicable CIRCLE ANSWER: YES NO

Form AEC-313 a (10-61) Page 2

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A — HUMAN USE

Form approved Budget Bureau No. 38-R0801

This page may be used for providing additional information. Please cross reference to specific items.

4(a) Con't

B. Iodine 131	B. Determination of plasma volumes and cardiac output. Cardiac scanning. Localization of brain tumors. Performance of placentograms
C. Iodine 131	C. Determination of thyroxine turnover.
D. Phosphorus 32	D. Treatment of polycythemia vera, leukemia, and bone metastases.
E. Gold 198	E. Intracavitary treatment of malignant effusions. Interstitial treatment of prostate carcinoma. Liver scanning.
F. Chromium 51	F. Determination of red cell mass, red cell survival time, and gastrointestinal bleeding. Spleen scanning.
G. Strontium 90	G. Treatment of superficial eye conditions.
H. Cobalt 60	H. Diagnosis of pernicious anemia.

4(b) Con't

B. Iodinated Human Serum Albumin.
C. Throxine.
D. Soluble PHosphate.
E. Colloidal.
F. Sodium Chromate and/or chromic chlorids.
G. Tracerlab Model RA-1 sealed medical applicator.
H. Vitamin B12

U.S. GOVERNMENT PRINTING OFFICE 1961 O—[illegible]

Form AEC-313a (1-56) Part 3

United States Atomic Energy Commission

APPLICATION FOR BYPRODUCT MATERIAL

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38-R70

This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9 (a) USING PHYSICIAN'S NAME	(b) NAME AND ADDRESS OF APPLICANT (if different from 9(a))
PAUL E. SIEBERT, Major MC Fitzsimons General Hospital	Denver 40, Colorado

10 CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN D (circle applicable numbers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function	161	1 2 3 4
	Treatment of hyperthyroidism	9	1 2 3 4
	Treatment of thyroid cancer	9	1 2 3 4
	Treatment of cardiac conditions	1	1 2 3 4
	Brain tumor localization		1 2 3 4
	Blood determinations	22	1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia	9	1 2 3 4
	Brain tumor localization		1 2 3 4
	Treatment of bone metastases		1 2 3 4
	Others: Eye Tumor Localization	2	1 2 3 4
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer	3	1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations	7	1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Other isotopes	Strontium 90	100	1 2 3 4
	Cobalt 60 Schilling Test	23	1 2 3 4
			1 2 3 4

Key to above numbers (column D) Active Participation and Discussion

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period including reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

11 TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING 480 hours

12 THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF

H. F. Bond, M. C.
Col. John A. Isherwood, M.C.$_{AT}$ Brooke General Hospital, Fort Sam Houston, Texas
(Name of physician (please print)) (Institution) (Address)

Form AEC-313a (11-63) 10 CFR 30 Page 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R085

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1 (a) USING PHYSICIAN'S NAME

John E. Canham, Lt Col, MC

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a). Include ZIP Code.)

U.S. Army Medical Research & Nutrition Laboratory
Fitzsimons General Hospital
Denver, Colorado 80240

2 THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER — (YES) NO

3 A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER — (YES) NO

PROPOSED DIAGNOSIS OR TREATMENT

4 (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary)

A. Carbon-14 — A. Nutrition and Metabolism Tracer Studies*
B. Carbon-14 — B. Nutrition and Metabolism Tracer Studies*
(See page 2)

(b) CHEMICAL FORM ADMINISTERED

A. Vitamins
B. Amino Acids
(See page 2)

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

As described in Appendix E, Procedures for Use of Radioactive Material, dated 16 July 1965.

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE

(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER — YES (NO)

(2) ON FILE WITH THE ISOTOPES BRANCH REFER TO APPLICATION NO 5-46-9, 5-46-10, 5-46-11, 5-46-12, 5-46-13 CIRCLE ANSWER — (YES) NO

5 PROPOSED DOSAGE SCHEDULE

(a) In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

As described in Inclosure entitled "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" attached to Application for Amendment to AEC Byproduct Material License 5-46-13(A66) dated 12 March 1964.

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER — YES (NO)

6 IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES:

Not applicable

T0502

7 THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. CIRCLE ANSWER — (YES) NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8 (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE Not applicable CIRCLE ANSWER — YES NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED Not applicable CIRCLE ANSWER — YES NO

Form AEC-313 a (10-61) PAGE 2

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICAT[illegible] FOR BYPRODUCT MATERIAL LICEN[illegible]

SUPPLEMENT A — HUMAN USE

Form approved. Budget Bureau No. 38-R080.1

This page may be used for providing additional information. Please cross reference to specific items.

4(a) cont.	C. Carbon-14	C. Nutrition and Metabolism Tracer Studies*
	D. Carbon-14	D. Nutrition and Metabolism Tracer Studies*
	E. Carbon-14	E. Nutrition and Metabolism Tracer Studies*
	F. Carbon-14	F. Nutrition and Metabolism Tracer Studies*
	G. Carbon-14	G. Nutrition and Metabolism Tracer Studies*
	H. Hydrogen-3	H. Nutrition and Metabolism Tracer Studies*
	I. Magnesium-28	I. Nutrition and Metabolism Tracer Studies*
	J. Calcium-47	J. Nutrition and Metabolism Tracer Studies*
	K. Calcium-45	K. Nutrition and Metabolism Tracer Studies*

*As described in Inclosure entitled "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" attached to Application for Amendment to AEC Byproduct Material License 5-46-13 (A66) dated 12 March 1964.

4(b) cont.	C. Lipids
	D. Acetate
	E. Carbohydrates
	F. Mevalonic Acid
	G. Bicarbonate or Carbon Dioxide
	H. Vitamins
	I. Magnesium Oxide, Magnesium Chloride, Magnesium Citrate
	J. Calcium Chloride
	K. Calcium Chloride

U.S. GOVERNMENT PRINTING OFFICE: 1961 O-[illegible]

Form AEC 313 a (10-61) Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A — HUMAN USE

Form approved Budget Bureau No. 38-R060.1

This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9 (a) USING PHYSICIAN'S NAME

John E. Canham MC

(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a)

Chief, Metabolic Division
U.S. ARMY Medical Research and Nutrition Laboratory
Fitzsimons General Hospital, Denver, Colorado 80240

10 CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN B (circle applicable numbers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function	20-25	(1) 2 3 4
	Treatment of hyperthyroidism		1 2 3 4
	Treatment of thyroid cancer		1 2 3 4
	Treatment of cardiac conditions		1 2 3 4
	Brain tumor localization		1 2 3 4
	Blood determinations		1 2 3 4
	Kidney function		1 2 3 4
	Others:		1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia	2	(1) 2 3 4
	Brain tumor localization		1 2 3 4
	Treatment of bone metastases		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
			1 2 3 4
Other Isotopes	Co^{60} and Vitamin B^{12}	24	(1) (2) 3 (4)
			1 2 3 4

Key to above numbers (column D)

Active Participation and Discussion in the

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period including reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

11 TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING _____ hours

12 THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF

Dr. John Coniglio PhD Vanderbilt University
Dr. Richard Bozian School of Medicine
Dr. Schmidt (Preceptor) U.S.A. Med. Res. & Nut. Lab.

(Signature)

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	U.S.Army Hosp. Wurzburg & Ft.San Vanderbilt Univ. School of Med.	2½ yrs 13½ mo	yes no	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Vandererbilt University School of Medicine	4½ mo formal 9 mo on job	Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Same as b. above		Yes No	Yes No
d. Biological effects of radiation	Same as b. above		Yes No	Yes No

9. 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}	0.5uc/patient or subject	Nutrition Clinic, Vanderbilt University.	9 months	Studies on Vitamin B_{12} requirements& half life in humans.
Co^{60}		Dept. Biochemistry Vanderbilt University.	4 months	Relationship B_{12} to Calcium in B_{12} absorptio
C-14, Cr-61, I-131 P-32, H3, K-42		" " "	4 months	Laboratory experience

10. RADIATION DETECTION INSTRUMENTS (Use supplemental sheets if necessary.)

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr./hr.)	WINDOW THICKNESS (mg./cm.²)	USE (Monitoring, surveying, measuring)

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE

12. FILM BADGES, DOSIMETERS, AND BIO ASSAY PROCEDURES USED. (For film badges, specify method of calibrating and processing, or name of supplier.)

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) Yes No

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

John E. Canham MC

Applicant named in item 1

Date

By:

Title of certifying official

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

U.S. GOVERNMENT PRINTING OFFICE: 1961 O—615365

Form AEC-313a (11-65) 10 CFR 30 PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R080

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1 (a) USING PHYSICIAN'S NAME

Robert H. Herman, Lt Col, MC

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a). Include ZIP Code.)

U.S. Army Medical Research & Nutrition Laboratory
Fitzsimons General Hospital
Denver, Colorado 80240

2 THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER	(YES)	NO
3 A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER	(YES)	NO

PROPOSED DIAGNOSIS OR TREATMENT

4 (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary)

A. Carbon-14 A. Nutrition and Metabolism Tracer Studies*
B. Carbon-14 B. Nutrition and Metabolism Tracer Studies*
(See page 2)

(b) CHEMICAL FORM ADMINISTERED

A. Vitamins
B. Amino Acids
(See page 2)

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

As described in Appendix E, Procedures for Use of Radioactive Material, dated 16 July 1965.

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE (1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER	YES	(NO)
(2) ON FILE WITH THE ISOTOPES BRANCH REFER TO APPLICATION NO 5-46-9, 5-46-10, 5-46-11, 5-46-12, 5-46-13 CIRCLE ANSWER	(YES)	NO

5 PROPOSED DOSAGE SCHEDULE

(a) In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

As described in Inclosure entitled "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" attached to Application for Amendment to AEC Byproduct Material License 5-46-13(A66) dated 12 March 1964.

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER	YES	(NO)

6 IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES.

Not applicable

7 THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE CIRCLE ANSWER	(YES)	NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8 (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE Not applicable CIRCLE ANSWER	YES	NO
(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED. Not applicable CIRCLE ANSWER	YES	NO

Form AEC-313 a (10-61)* PAGE 2

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A — HUMAN USE

Form approved. Budget Bureau No. 38-R0801

This page may be used for providing additional information. Please cross reference to specific items.

4(a) cont.	C. Carbon-14	C. Nutrition and Metabolism Tracer Studies*
	D. Carbon-14	D. Nutrition and Metabolism Tracer Studies*
	E. Carbon-14	E. Nutrition and Metabolism Tracer Studies*
	F. Carbon-14	F. Nutrition and Metabolism Tracer Studies*
	G. Carbon-14	G. Nutrition and Metabolism Tracer Studies*
	H. Hydrogen-3	H. Nutrition and Metabolism Tracer Studies*
	I. Magnesium-28	I. Nutrition and Metabolism Tracer Studies*
	J. Calcium-47	J. Nutrition and Metabolism Tracer Studies*
	K. Calcium-45	K. Nutrition and Metabolism Tracer Studies*

*As described in Inclosure entitled "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" attached to Application for Amendment to AEC Byproduct Material License 5-46-13 (A66) dated 12 March 1964.

4(b) cont.	C. Lipids
	D. Acetate
	E. Carbohydrates
	F. Mevalonic Acid
	G. Bicarbonate or Carbon Dioxide
	H. Vitamins
	I. Magnesium Oxide, Magnesium Chloride, Magnesium Citrate
	J. Calcium Chloride
	K. Calcium Chloride

U.S. GOVERNMENT PRINTING OFFICE : 1961 O—615965

Form AEC-313 a (10-61) Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R060.1

This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9. (a) USING PHYSICIAN'S NAME

Robert H. Herman
Major, MC
USAMRNL, FGH, Denver, Colo.

(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a))

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN B (circle applicable numbers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function	Approx 50	(1) 2 (3) (4)
	Treatment of hyperthyroidism	Approx 50	(1) 2 (3) (4)
	Treatment of thyroid cancer		1 2 3 4
	Treatment of cardiac conditions		1 2 3 4
	Brain tumor localization		1 2 3 4
	Blood determinations		1 2 3 4
	Kidney function		1 2 3 4
	Others:		1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia	Approx 4	(1) 2 (3) (4)
	[illegible] tumor localization		1 2 3 4
	[illegible]ent of bone metastases		1 2 3 4
	[illegible] Treatment of thrombocythemia	Approx 1	(1) 2 (3) (4)
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites	Approx 1	(1) 2 (3) (4)
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations	Approx 20	(1) (2) (3) (4)
	Others:		1 2 3 4
			1 2 3 4
			1 2 3 4
Other Isotopes			1 2 3 4
			1 2 3 4

Key to above numbers (column D)

Active Participation and Discussion in the

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period including reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

11. TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING _____ hours At least 100 hrs over a 3 year residency in internal medicine and 1 1/2 yrs doing cl.invest. in metabolic & endocrine diseases

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF Appropriate staff members at Walter Reed General Hospital.

(Name of physician (preceptor)) AT (Institution)

(Signature)

Form AFC-313 (5-58)

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	Walter Reed Army Institute of Research	1 yr	(Yes) No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Walter Reed Army Institute of Research	1 yr	(Yes) No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Ill. Instit. of Technology	4 yrs	Yes (No)	(Yes) No
d. Biological effects of radiation	Walter Reed Army Institute of Research & Walter Reed Gen Hosp	(incl. res. in Int. Med) 5 yrs	(Yes) No	(Yes) No

9. EXPERIENCE WITH RADIATION (Actual use of radioisotopes or equivalent experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{45}Ca		WRAIR	9 mos	Lab. res.
^{59}Fe		WRAIR	1 month	Lab. res.
^{51}Cr (See attached)		Walter Reed Genl Hosp.	3 years	Blood vol. deter. in patients

10. RADIATION DETECTION INSTRUMENTS (Use supplemental sheets if necessary)

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)
Scintillation counter	3	^{14}C			Measuring
Gas-flow B-counter	3	^{14}C			Measuring
		^{45}Ca			Measuring
Gamma counter	1	^{59}Fe			Measuring
4 Pi-Paper scanner	2	^{14}C			Measuring
Thin-layer chromatogram scanner	1	^{14}C			Measuring

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE

Done by personnel at U.S. Army Institute of Research and Univ. of Pennsylvania.

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED (For film badges, specify method of calibrating and processing, or name of supplier)

Film badges provided by radiation safety office at WRAIR and the Univ. of Penn.

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) Yes No

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

Robert H. Yeomans

Applicant named in item 1

Date 22 July 1965

By: [illegible]

Title of certifying official

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

U.S. GOVERNMENT PRINTING OFFICE : 1961 O—611965

Form AEC-313 a (10-61) Page 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R030.1

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME: Joseph L. Marcarelli, Maj,MC

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a)): U. S. Army Medical Research & Nutrition Laboratory, Fitzsimons General Hospital, Denver, Colorado 80240

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER — (YES) NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER — (YES) NO

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary)

A. Iodine 131 A. Diagnosis of thyroid function and thyroid scanning. Treatment of hyperthyroidism, cardiac conditions and thyroid carcinoma

(See page 2)

(b) CHEMICAL FORM ADMINISTERED

A. Iodide

(See page 2)

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

As described in Appendix to Form AEC-313a submitted as part of application for AEC Byproduct Material License 5-46-13(A66) dated 6 December 1963

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE

(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER — YES (NO)

(2) ON FILE WITH THE ISOTOPES EXTENSION REFER TO APPLICATION NO 5-46-9, 5-46-10, 5-46-11, 5-46-12, 5-46-13 CIRCLE ANSWER — (YES) NO

5. (a) PROPOSED DOSAGE SCHEDULE.—In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

As described in Appendix to Form AEC-313a submitted as part of application for AEC Byproduct Material License 5-46-13(A66) dated 6 December 1963

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER — YES (NO)

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES:

Not Applicable

7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. CIRCLE ANSWER — (YES) NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE Not Applicable CIRCLE ANSWER — YES NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED Not Applicable CIRCLE ANSWER — YES NO

Form AEC-313 a (10-61) Page 2

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A — HUMAN USE

Form approved. Budget Bureau No. 38-R0601

This page may be used for providing additional information. Please cross reference to specific items.

4(a) Con't

B.	Iodine 131	B. Determination of plasma volumes and cardiac output. Cardiac scanning. Localization of brain tumors. Performance of placentograms.
C.	Iodine 131	C. Determination of renal function.
D.	Iodine 131	D. Determination of liver function. Liver scanning.
E.	Iodine 131	E. Determination of fat absorption.
F.	Iodine 131	F. Determination of liver and gallbladder function.
G.	Iodine 131	G. Determination of protein loss. Brain scanning.
H.	Iodine 131	H. Determination of thyroxine turnover.
I.	Iodine 125	I. Diagnosis of Thyroid function and thyroid scanning.
J.	Iodine 125	J. Determination of plasma volumes.
K.	Iodine 125	K. Determination of renal function.
L.	Iodine 125	L. Determination of liver function.
M.	Iodine 125	M. Determination of fat absorption.
N.	Iodine 125	N. Determination of liver and gallbladder function.
O.	Iodine 125	O. Determination of thyroxine turnover.
P.	Phosphorus 32	P. Treatment of polycythemia vera, leukemia, and bone metastases.
Q.	Phosphorus 32	Q. Intracavitary treatment of malignant effusions.
R.	Gold 198	R. Intracavitary treatment of malignant effusions. Insterstitial treatment of prostate carcinoma. Liver scanning.
S.	Chromium 51	S. Determination of red cell mass, red cell survival time, and gastrointestinal bleeding. Spleen scanning.
T.	Cobalt 58	T. Diagnosis of pernicious anemia.
U.	Cobalt 60	U. Diagnosis of pernicious anemia.
V.	Iron 59	V. Determination of iron turnover.
W.	Mercury 197	W. Kidney and brain scanning.
X.	Mercury 203	X. Kidney and brain scanning.
Y.	Hydrogen 3	Y. Determination of total body water.
Z.	Sodium 24	Z. Determination of total exchangeable sodium.
AA.	Selenium 75	AA. Pancreatic scanning.
BB.	Xenon 133	BB. Determination of pulmonary function.
CC.	Strontium 85	CC. Bone scanning.
DD.	Strontium 90	DD. Treatment of superficial eye conditions.

4(b) Con't

B. Iodinated Human Serum Albumin	O. Colloidal Chromic Phosphate
C. Hippuran	R. Colloidal
D. Rose Bengal	S. Sodium Chromate and/or Chromic Chloride
E. Triolein and/or Oleic Acid	T. Vitamin B12
F. Cholografin	U. Vitamin B12
G. p-Toluidine polyvinylpyrrolidone	V. Ferric Chloride and/or Ferrous Citrate
H. Thyroxine	W. Chlormerodrin
I. Iodide	X. Chlorerodrin
J. Iodinated Human Serum Albumin	Y. Water
K. Hippuran	Z. Sodium Chloride
L. Rose Bengal	AA. Selenomethionine
M. Triolein and/or Oleic Acid	BB. Gas
N. Cholografin	CC. Strontium Nitrate
O. Throxine	DD. Tracerlab Model RA-1 Sealed Medical Applicator
P. Soluble Phosphate	

Form AEC-313 (3-56) Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38-R080.1

This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9. (a) USING PHYSICIAN'S NAME: MARCARELLI, JOSEPH L.

(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a))

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	* (C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN D (circle applicable numbers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function	2500	(1) (2) (3) (4)
	Treatment of hyperthyroidism	50	(1) (2) (3) (4)
	Treatment of thyroid cancer	25	(1) (2) (3) (4)
	Treatment of cardiac conditions	5	(1) (2) (3) (4)
	Brain tumor localization	0	1 2 3 4
	Blood determinations RISA	100	(1) (2) (3) (4)
	Others: Hippuran	75	(1) (2) (3) (4)
	over Rose Bengal Liver Studies	5	(1) (2) (3) (4)
P-32 Soluble	Treatment of polycythemia and leukemia	50	(1) (2) (3) (4)
	Brain tumor localization	0	1 2 3 4
	Treatment of bone metastases	5	(1) (2) (3) (4)
	Others: Rx of Lymphomas	5	(1) (2) (3) (4)
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer	0	1 2 3 4
	Treatment of cervical cancer	0	1 2 3 4
	Treatment of pleural effusions and/or ascites	0	1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer	5	(1) (2) (3) (4)
	Treatment of cervical cancer	0	1 2 3 4
	Treatment of pleural effusions and/or ascites	10	(1) (2) (3) (4)
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations	100	(1) (2) (3) (4)
	Others:	0	1 2 3 4
			1 2 3 4
Other Isotopes	Co 60 - Schilling Test	75	(1) (2) (3) (4)
	Fe 59 - Ferrokinetics	25	(1) (2) (3) (4)
			1 2 3 4

Key to above numbers (column D) Active Participation and Discussion

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period including reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most effective diagnostic and/or therapeutic techniques for this radioisotope use.

11. TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING 4500 hours

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF

E. Stenberg, Col, MC
F. Huycke, Maj., MC
F. Zanca, Col., MC
(Name of physician (preceptor))

AT Tripler Gen. Hosp., Honolulu
Walter Reed Gen. Hosp., Washington
Brooke Gen. Hosp., San Antonio
(Institution)

(Signature)

Form AEC-313 a (3-56) Page 4

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 29-R060.1

This page may be used for providing additional information.

+ I_{131} (Continued)		
Triolein, Oleic Acid - Intest. Absorp.	25	(1) (2) (3) (4)
T_3 RBC Uptake	50	(1) (2) (3) (4)
++ Other (Continued)		
Hg - 203	0	
I-125	0	
Se-75	0	
Sr-85	0	
Hg-197	0	
Xe-133		

*Estimated figures

I certify that I have had the following training and experience in radioisotopes:

1. Approximately 3 months during residency in medicine at Tripler between 1957 - 1960

2. 2 months at Walter Reed General Hospital in 1961

3. Chief Radioisotope Clinic at Brooke General Hospital from 1961 - 1963

   Chief, Nuclear Emergency Team (NETOPS) - Brooke Army Medical Center 1961 - 1963

   Completed 1 month NETOPS course at Sandia Base in 1963

   Completed 1 week Nuclear Mass Casualty Course at Sandia in 1963

Request that Joseph L. Marcarelli, Maj MC, Director of Clinical Research, Fitzsimons General Hospital, be authorized to use any by product material with atomic number 1 to 83 inclusive in animal and in vitro applications, and all radioisotopes specified in license No. 5-46-13 for human use according to the limitations of that license.

Joseph L. Marcarelli

JOSEPH L. MARCARELLI
Major MC
Director of Clinical Research

27 July 1965

APPROVED: Radioisotope Committee
Fitzsimons General Hospital

Edwin L. Overholt

EDWIN L. OVERHOLT
COL MC
Chief, Medical Service

James A. Smith

JAMES A. SMITH
Colonel MC
Acting Commander

Form AEC-313 a (10-61) PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R080.1

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME: Leonard C. Griff, Capt, MC

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a)): U. S. Army Medical Research & Nutrition Laboratory, Fitzsimons General Hospital, Denver, Colorado 80240

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER	(YES)	NO
3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER	(YES)	NO

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary): A. Iodine 131 (See page 2)

A. Diagnosis of thyroid function and thyroid scanning. Treatment of hyperthyroidism, cardiac conditions and thyroid carcinoma.

(b) CHEMICAL FORM ADMINISTERED: A. Iodide (See page 2)

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL: As described in Appendix to Form AEC-313a submitted as part of application for AEC Byproduct Material License 5-46-13(A66) dated 6 December 1963.

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE (1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER	YES	(NO)
(2) ON FILE WITH THE ISOTOPES EXTENSION REFER TO APPLICATION NO 5-46-9, 5-46-10, 5-46-11, 5-46-12, 5-46-13 CIRCLE ANSWER	(YES)	NO

5. (a) PROPOSED DOSAGE SCHEDULE. In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary): As described in Appendix to Form AEC 313a submitted as part of application for AEC Byproduct Material License 5-46-13(A66) dated 6 December 1963.

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER	YES	(NO)

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES: Not Applicable

7. THE PROPOSED USP OR BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. CIRCLE ANSWER	(YES)	NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE Not Applicable CIRCLE ANSWER	YES	NO
(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED. Not Applicable CIRCLE ANSWER	YES	NO

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICE

SUPPLEMENT A — HUMAN USE

Form approved
Budget Bureau No. 38-R080.1

This page may be used for providing additional information. Please cross reference to specific items.

4(a) Con't

B. Iodine 131	B. Determination of plasma volumes and cardiac output. CArdiac scanning. Localization of brain tumors. Performance of placentograms.
C. Iodine 131	C. Determination of renal function.
D. Iodine 131	D. Determination of liver function. Liver scanning.
E. Iodine 125	E. Determination of renal function.
F. Gold 198	F. Intracavitary treatment of malignant effusions. Interstitial treatment of prostate carcinoma. Liver scanning.
G. Chromium 51	G. Determination of red cell mass, red cell survival time and gastrointestinal bleeding. Spleen scanning.
H. Cobalt 58	H. Diagnosis of pernicious anemia.
I. Cobalt 60	I. Diagnosis of pernicious anemia.
J. Mercury 203	J. Kidney and brain scanning.
K. Strontium 85	K. Bone scanning.

4(b) Con't)

B. Iodinated Human Serum Albumin.
C. Hippuran
D. Rose Bengal
E. Hippuran
F. Colloidal
G. Sodium Chromate and/or Chromic Chloride
H. Vitamin B12
I. Vitamin B12
J. Chlormerodrin
K. Strontium Nitrate

U.S. GOVERNMENT PRINTING OFFICE : 1961 O—615965

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UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

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This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9. (a) USING PHYSICIAN'S NAME	(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a))

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN D (circle applicable numbers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function		1 2 3 4
	Treatment of hyperthyroidism		1 2 3 4
	Treatment of thyroid cancer		1 2 3 4
	Treatment of cardiac conditions		1 2 3 4
	Brain tumor localization		1 2 3 4
	Blood determinations		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia		1 2 3 4
	Brain tumor localization		1 2 3 4
	Treatment of bone metastases		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Other Isotopes			1 2 3 4
			1 2 3 4
			1 2 3 4

Key to above numbers (column D) Active Participation and Discussion

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period including reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

11. TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING _____ hours

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF

_____ AT _____ _____
(Name of physician (preceptor)) (Institution) (Signature)

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UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38-R080.1

This page may be used for providing additional information.

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D)
I-131	Renogram with hippuran	1	(1)(2)(3)(4)
	PBI conversion	2	(1)(2)(3)(4)
	Sodium iodiranide	2	(1)(2)(3)(4)
Other Isotopes			
	Tc^{99} brain scan	5	(1)(2)(3)(4)
	$Iridium^{192}$ interstitial	1	(1)(2)(3)(4)
	Sr^{90} applicator	15	(1)(2)(3)(4)

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UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved Budget Bureau No. 38-R080

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME

David A. Zakim, Capt, MC

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a). Include ZIP Code.)

U.S. Army Medical Research & Nutrition Laboratory
Fitzsimons General Hospital
Denver, Colorado 80240

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER — (YES) NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER — (YES) NO

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary):

A. Carbon-14 A. Nutrition and Metabolism Tracer Studies*
B. Carbon-14 B. Nutrition and Metabolism Tracer Studies*
(See page 2)

(b) CHEMICAL FORM ADMINISTERED

A. Vitamins
B. Amino Acids
(See page 2)

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL

As described in Appendix E, Procedures for Use of Radioactive Material, dated 16 July 1965.

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE
(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER — YES (NO)

(2) ON FILE WITH THE ISOTOPES BRANCH
REFER TO APPLICATION NO 5-46-9, 5-46-10, 5-46-11, 5-46-12, 5-46-13 CIRCLE ANSWER — (YES) NO

5. PROPOSED DOSAGE SCHEDULE

(a) In millicuries for internally administered byproduct material other than discrete fixed sources, and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

As described in Inclosure entitled "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" attached to Application for Amendment to AEC Byproduct Material License 5-46-13(A66) dated 12 March 1964.

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER — YES (NO)

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES.

Not applicable

7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. CIRCLE ANSWER — (YES) NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE Not applicable CIRCLE ANSWER — YES NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED. Not applicable CIRCLE ANSWER — YES NO

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UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICEN

SUPPLEMENT A — HUMAN USE

Form approved. Budget Bureau No. 38-R080 1

This page may be used for providing additional information. Please cross reference to specific items.

4(a) cont.	C. Carbon-14	C. Nutrition and Metabolism Tracer Studies*
	D. Carbon-14	D. Nutrition and Metabolism Tracer Studies*
	E. Carbon-14	E. Nutrition and Metabolism Tracer Studies*
	F. Carbon-14	F. Nutrition and Metabolism Tracer Studies*
	G. Carbon-14	G. Nutrition and Metabolism Tracer Studies*
	H. Hydrogen-3	H. Nutrition and Metabolism Tracer Studies*
	I. Magnesium-28	I. Nutrition and Metabolism Tracer Studies*
	J. Calcium-47	J. Nutrition and Metabolism Tracer Studies*
	K. Calcium-45	K. Nutrition and Metabolism Tracer Studies*

*As described in Inclosure entitled "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" attached to Application for Amendment to AEC Byproduct Material License 5-46-13 (A66) dated 12 March 1964.

4(b) cont.	C. Lipids
	D. Acetate
	E. Carbohydrates
	F. Mevalonic Acid
	G. Bicarbonate or Carbon Dioxide
	H. Vitamins
	I. Magnesium Oxide, Magnesium Chloride, Magnesium Citrate
	J. Calcium Chloride
	K. Calcium Chloride

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UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

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This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9. (a) USING PHYSICIAN'S NAME	(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a))
David S. Zakim, Capt. MC USAMRDL, METABOLIC DIVISION	

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN B (circle applicable numbers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function	Approx 50	(1) 2 (3) (4)
	Treatment of hyperthyroidism	Approx 50	(1) 2 (3) (4)
	Treatment of thyroid cancer		1 2 3 4
	Treatment of cardiac conditions		1 2 3 4
	Brain tumor localization		1 2 3 4
	Blood determinations	Approx 50	(1) 2 (3) (4)
	Kidney function		1 2 3 4
	Others:		1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia	Approx 10	(1) 2 (3) (4)
	Brain tumor localization		1 2 3 4
	Treatment of bone metastases		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites	Approx 5	(1) 2 (3) (4)
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites	Approx 5	(1) 2 (3) (4)
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Other Isotopes	Co^{60} Schilling test	Approx 100	(1) (2) (3) (4)
			1 2 3 4
			1 2 3 4

Key to above numbers (column D)

Active Participation and Discussion in the

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period including reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

11. TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING 700 hours

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF The Dept. of Medicine Cornell Univ., New York Hosp. Med. Center during 4 yrs of intership and residency training. AT

(Name of physician (preceptor)) (Institution) (Signature)

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

9. EXPERIENCE WITH RADIATION (Continued)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXP.	TYPE OF USE
^{14}C-progesterone		WRAIR and Walter Reed Gen Hosp.	1 month	Metabolism of adrenal steroids in pati[illegible] of urinol[illegible]
^{14}C- Inulin	20,000 cpm/flask	W[illegible]	[illegible] yrs	Lab. re[illegible]
$^{14}CO_2$-		WRAIR	4 yrs	Lab. re[illegible]
^{14}C- Cholesterol	Approx. 10^6 dpm	Univ. of Penn. Dept of Biochemistry	3 yrs	Lab. resea[illegible]
^{14}C-Steroids (Various kinds)	Approx. 10^6 dpm	Univ. of Penn. Dept of Biochemistry	3 yrs	Lab. research
^{14}C-Iodobutyric acid	Approx. 10^7 dpm	Univ. of Penn. Dept of Biochemistry	3 yrs	Chemical [illegible] of ^{14}C-[illegible] steroids

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TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	State Univ. of New York College of Medicine	1 yr	(Yes) No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Same as above	1 yr	(Yes) No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Same as above	1 yr	(Yes) No	Yes No
d. Biological effects of radiation	Same as Above	1 yr	Yes No	(Yes) No

9. EXPERIENCE WITH RADIATION. (Actual use of radioisotopes or equivalent experience.)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
C-14	1 mc	The New York Hosp. Med. Center.	2 yrs	Metabolic experiments in animals
Cl-36	5 mc	State Unic. of N.Y.	1 yr	
Na-24	5 mc	College of Medicine		

10. RADIATION DETECTION INSTRUMENTS (Use supplemental sheets if necessary.)

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. (For film badges, specify method of calibrating and processing, or name of supplier.)

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) Yes No

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

Applicant named in item 1 David S. Zakim, Capt

Date 31 December 1965

By: Charles G. Liddle, Capt.

Title of certifying official Ch, Radioisotope Lab. USAMRNL Physiology Division

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

U.S. GOVERNMENT PRINTING OFFICE 1961 O—615965

6(a) Byproduct Material (Element and Mass Number)	6(b) Chemical and/or Physical Form	Maximum Amount of Radioactivity which License May Possess at Any One Time
M. Iodine 125	M. Trolein and/or Oleic Acid	M. 1 millicurie
N. Iodine 125	N. Cholografin	N. 1 millicurie
O. Iodine 125	O. Thyroxine	O. 1 millicurie
P. Phosphorus 32	P. Soluble Phosphate	P. 25 millicuries
Q. Phosphorus 32	Q. Colloidal Chromic Phosphate	Q. 25 millicuries
R. Gold 198	R. Colloidal	R. 250 millicuries
S. Chromium 51	S. Sodium Chromate and/or Chromic Chloride	S. 4 millicuries
T. Cobalt 58	T. Vitamin B12	T. 10 microcuries
U. Cobalt 60	U. Vitamin B12	U. 10 microcuries
V. Iron 59	V. Ferric Chloride and/or Ferrous Citrate	V. 1 millicurie
W. Mercury 197	W. Chlormerodrin	W. 10 millicuries
X. Mercury 203	X. Chlormerodrin	X. 10 millicuries
Y. Hydrogen 3	Y. Water	Y. 25 millicuries
Z. Sodium 24	Z. Sodium Chloride	Z. 1 millicurie
AA. Selenium 75	AA. Selenomethionine	AA. 10 millicuries
BB. Xenon 133	BB. Gas	BB. 2 curies
CC. Strontium 85	CC. Strontium Nitrate	CC. 1 millicurie
DD. Strontium 90	DD. Tracerlab Model RA-1 Sealed Medical Applicator	DD. 25 millicuries
EE. Any byproduct material with Atomic Nos. 1-83, inclusive	EE. Any	EE. 500 millicuries of each exceptHydrogen 3-5 curies. Total not to exceed 10 curies
FF. Carbon 14	FF. Vitamins	FF. 10 millicuries
GG. Carbon 14	GG. Amino Acids	GG. 10 millicuries
HH. Carbon 14	HH. Lipids	HH. 10 millicuries
II. Carbon 14	II. Acetate	II. 10 millicuries
JJ. Carbon 14	JJ. Carbohydrates	JJ. 10 millicuries
KK. Carbon 14	KK. Mevalonic Acid	KK. 10 millicuries
LL. Carbon 14	LL. Bicarbonate or CArbon Dioxide	LL. 10 millicuries
MM. Hydrogen 3	MM. Vitamins	MM. 50 millicuries
NN. Magnesium 28	NN. Magnesium Oxide Magnesium Chloride Magnesium Citrate	NN. 10 millicuries
OO. Calcium 47	OO. Calcium Chloride	OO. 10 millicuries
PP. Calcium 45	PP. Calcium Chloride	PP. 10 millicuries
QQ. Carbon 14	QQ. Any	*QQ. 1 millicurie
RR. Iodine 131	RR. Any	*RR. 1 millicurie
SS. Iodine 125	SS. Any	*SS. 1 millicurie

APPENDIX C (Con't)

TT. Chromium 51	TT. Any	*TT. 1 millicurie
UU. Hydrogen 3	UU. Any	*UU. 5 millicuries
VV. Sulfur 35	VV. Any	*VV. 5 millicuries
WW. Bromine 82	WW. Any	*WW. 5 millicuries

*Quantities of radioisotopes listed in QQ through WW are those quantities authorized for use at the summit of Pikes Peak, Colorado. These quantities represent a portion of the quantities authorized in EE, not additional authorizations. TT through WW represent an amendment. See Appendix G.

Continuation of Item 7 APPENDIX D 21 June 1966

Describe Purpose for Which Byproduct Material Will be Used:

A. Diagnosis of thyroid function and thyroid scanning. Treatment of hyperthyroidism, cardiac conditions and thyroid carcinoma.
B. Determination of plasma volumes and cardiac output. Cardiac scanning. Localization of brain tumors. Performance of placenlograms.
C. Determination of renal function.
D. Determination of liver function. Liver scanning.
E. Determination of fat absorption.
F. Determination of liver and gallbladder function.
G. Determination of protein loss. Brain scanning.
H. Determination of thyroxine turnover.
I. Diagnosis of thyroid function and thyroid scanning.
J. Determination of plasma volumes.
K. Determination of renal function.
L. Determination of liver function.
M. Determination of fat absorption.
N. Determination of liver and gallbladder function.
O. Determination of thyroxine turnover.
P. Treatment of polycythemia vera, leukemia and bone metastases.
Q. Intracavitary treatment of malignant effusions.
R. Intracavitary treatment of malignant effusions. Interstitial treatment of prostate carcinoma. Liver scanning.
S. Determination of red cell mass, red cell survival time and gastrointestinal bleeding. Spleen scanning.
T. Diagnosis of pernicious anemia.
U. Diagnosis of pernicious anemia.
V. Determination of iron turnover.
W. Kidney and brain scanning.
X. Kidney and brain scanning.
Y. Determination of total body water.
Z. Determination of total exchangeable sodium.
AA. Pancreatic scanning.
BB. Determination of pulmonary function.
CC. Bone scanning.
DD. Treatment of superficial eye conditions.
EE. Laboratory research in vitro and in lower animals.
FF. - PP. Nutrition and metabolism tracer studies as described in Inclosure entitled "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" attached to application for amendment to AEC Byproduct Material License 5-46-13 (A66) dated 12 March 1964..

Appendix D (Con't)

QQ. - SS. Metabolic studies in lower animals at the summit of Pikes Peak, Colorado as described in Appendix I to Application for Amendment to AEC Byproduct Material License 5-46-13(A66) dated 12 August 1964, and Appendix I to Application for Amendment to AEC Byproduct Material License 5-46-13(A66) dated 4 June 1965.

TT. - WW. Metabolic studies in lower animals at the summit of Pikes Peak, Colorado. Request AEC Byproduct Material License be amended to permit the use of these radioisotopes at the summit of Pikes Peak, Colorado (see Appendix G).

APPENDIX E

U. S. ARMY MEDICAL RESEARCH AND NUTRITION LABORATORY
FITZSIMONS GENERAL HOSPITAL
DENVER, COLORADO

16 July 1965

PROCEDURES FOR USE OF RADIOACTIVE MATERIAL

References:

Title 10 C.F.R., Part 20
AR 40-37, 40-414, 40-440, 55-55, 70-25, 385-30, 711-16, 755-380

National Bureau of Standards Handbooks

No. 48 Control and Removal of Radioactive Contamination in Laboratories
No. 49 Recommendations for Waste Disposal of Phosphorus-32 and Iodine-131 for Medical Users
No. 51 Radiological Monitoring Methods and Instruments
No. 53 Recommendations for the Disposal of Carbon-14 wastes
No. 59 Permissible Dose From External Sources of Radiation
No. 65 Safe Handling of Bodies Containing Radioactive Isotopes
No. 69 Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air and in water for Occupational Exposure
No. 78 Report of the International Commission Radiological Units and Measurements, 1959.
No. 80 A Manual of Radioactive Procedures

SECTION I

GENERAL

1. The purpose of this memorandum is to insure the safe handling of all radioactive materials within the United States Army Medical Research and Nutrition Laboratory.

2. The Radiation Safety Officer of Fitzsimons General Hospital and U.S. Army Medical Research and Nutrition Laboratory (hereafter designated only "Radiation Safety Officer") shall have the responsibility for the enforcement of all phases of radiation safety within USAMRNL.

3. These procedures are published as a guide and must not be construed to be an amendment or change to any existing federal regulation, Army regulation, or local regulation governing the use of radioactive material.

SECTION II

RADIOISOTOPE COMMITTEE

4. The U.S. Army Medical Research and Nutrition Laboratory operates jointly with Fitzsimons General Hospital under the same General Atomic Energy Commission License. Use of radioisotopes, within the limitations of the AEC License, is controlled by a Radioisotope Committee consisting of Fitzsimons General Hospital personnel as well as U.S. Army Medical Research and Nutrition Laboratory personnel. The persons making up the Radioisotope Committee and the functions of the committee are outlined in AR 40-37. The committee will be responsible for proper handling, storage and disposal of radioactive materials. In addition, the committee will:

a. Recommend changes to the SOP concerning periodic monitoring and enforcement of safety measures in the handling of radioactive material.

b. Review and grant permission for, or disapproval of, the use of radioactive material.

c. Certify individual users for each type of procedure with each individual radioisotope and insure that a copy of such certification is placed in the appropriate users' 201 file. Current records of these approved users, documenting the qualifications and limitations of each, will be maintained.

d. Prescribe special conditions which may be necessary to include and give advice concerning proposed studies where it is needed.

e. Review records and receive reports from the Radiological Protection Officer and recommend corrective action when indicated.

f. Make recommendations for improvement of present laboratory facilities and for expansion of the laboratories in accordance with needs.

g. Hold meetings at the call of the Chairman and report in writing to the Commanding Officer, the results of its deliberation.

SECTION III

HAZARD CONTROL

5. The Chief of the Radioisotope Branch, USAMRNL, shall instruct, direct, and supervise all individuals at USAMRNL working with or near radioactive materials in the observance of radiological safety.

6. Each individual working within or near radioactive material (or any employee who will possibly be exposed to ionizing radiation) will be issued a film badge. Before a film badge will be issued, each individual must read both CFR, Title 10, Part 10, and the laboratory SOP, and certify in writing that he has read and understands both.

7. Permission to handle, administer, or assist in the administration of radioactive materials under AEC General License in USAMRNL may be granted only by the Radioisotope Committee. This permission may be denied or withdrawn from any person who, in the opinion of the Radioisotope Committee or on the advice of the Radiation Safety Officer, is inadequately trained in the handling and use of radioactive materials, or is guilty of any breach of discipline as concerns the handling and use of radioactive materials so as to incur real or possible hazard to himself or others.

8. The safety rules listed hereinafter are to be observed. However, it is emphasized that mere following of the rules will not eliminate all possible hazards associated with the handling of radioactive materials.

9. The protection rules are based upon assumed long-term whole-body exposure to ionizing radiation by personnel whose duties involve regular handling of radioactive material or regular use of x-ray equipment. These rules apply to all persons occupationally employed using any source of ionizing radiation in a controlled area or those incidentally exposed as a result of such use, under any condition. A controlled area is one in which the occupational exposure of personnel to radiation or to radioactive material is under the supervision of a Radiation Protection Officer. (This implies that a controlled area is one that requires control of access, occupancy and working condition for radiation protection purposes.)

SECTION IV

PROCUREMENT, STORAGE AND ADMINISTRATION

10. All radioactive materials for use in USAMRNL will be procured through the Radioisotope Branch by the Supply Officer, USAMRNL.

11. The Supply Officer, USAMRNL, will be responsible for the storage and handling of the contents of each shipment of radioactive material until such time as the shipment is delivered to the Chief, Radioisotope Branch, who will be responsible for the maintenance of records pertaining thereto.

12. The Radiation Safety Officer will direct the storage and handling of the contents of each shipment of radioactive material after it has been delivered to him or his designated representative in the Radioisotope Laboratory, and will be responsible for the maintenance of the records pertaining thereto.

13. The storage area will be neat and segregated by type emission. Gamma emitting isotopes will be stored so that the radiation level at the edge of the storage area does not exceed 2 mr/hr.

14. The Radiation Safety Officer will be responsible for the handling and disposal of radioisotope-contaminated liquid and solid wastes of the Radioisotope Laboratory in accordance with the recommended procedures found in Part 20, Title 10 and Army regulations concerning such matters.

SECTION V

SAFETY RULES

15. In order to avoid undue exposure to ionizing radiation, unauthorized personnel will not enter the Laboratory of the Radioisotope Branch except when accompanied by an authorized person.

16. Only persons specifically authorized to do so by the Radioisotope Committee will handle any shipment of radioactive material or any part thereof after it has been delivered to the Radioisotope Branch.

17. Only persons specifically authorized to do so by the Radioisotope Committee and/or under the supervision of the Radiation Safety Officer will prepare or administer a dose of any radioactive material after it has been delivered to the Radioisotope Laboratory.

18. In all rooms where radioactive materials are being used, the following regulations shall be in effect:

a. There will be no eating or drinking, and no application of cosmetics.

b. Smoking is not permitted while active material is being handled.

c. There will be absolutely no mouth pipetting of radioactive material in the laboratory under any circumstances.

d. Under no circumstances will radioactive waste be handled or disposed of by the janitorial staff.

e. Rubber gloves will be worn at all times when radioactive material is being handled. (Except sealed, or capped containers of radioactive materials.)

f. All gloves, protective clothing, instruments, and glassware will be checked for radioactive-contamination with a laboratory monitor after using, and, if contaminated, will be placed in the appropriate receptacle to await decontamination.

g. All contaminated glassware, instruments, pipettes, and waste incurred in any radioisotope experiment or study will be policed and placed in an appropriate receptacle or sink by the persons performing the experiment or study.

h. At the end of each work period the hands shall be carefully washed and tested for contamination with an instrument of suitable sensitivity.

i. Before placing radioactive material in any container, the container will be clearly labeled with radioactive caution tape of yellow and magenta to show the particular radioactive material, the concentration in microcuries or millicuries per unit volume weight as of some particular date, and the identifying initials of the person preparing the material.

j. Work surfaces will be covered with absorbent paper. The work in hoods will be similarly performed with absorbent paper. The work bench will be equipped with wiping papers for the prompt removal of spills.

k. When using radioactive material, special equipment suitable for the type and level of activity being used will be used for each type of operation. This will include handling tools such as tongs, forceps, trays, and mechanical holders. When the isotopes concerned are primarily beta emitters, efficient use can be made of transparent plastic shields. Containers for liquid samples will be reinforced by an outer unbreakable container.

l. No individual shall knowingly expose himself, or cause others to be exposed, to more than 0.02 rem in any working day.

m. All laboratory operations with more than low level activity will be conducted in hoods.

19. The sinks in the laboratory portion of the Radioisotope Laboratory will not be used for purposes of performing personal toilets, except that the non-contaminated sinks may be used for the purpose of hand washing after the removal of rubber gloves.

20. No water for drinking purposes will be obtained from the laboratory portion of the Radioisotope Branch.

SECTION VI

RADIOACTIVE WASTE

21. The Radiation Safety Officer is responsible for the disposal of all radioactive waste within USAMRNL. Such disposal shall be accomplished under all existing regulations listed in Part 20, Title 10, NBS Handbooks, and Army Regulations.

22. For persons other than Radioisotope personnel:

a. Solid radioactive waste shall be placed in waterproof disposable containers and deposited in the container marked with a Radiation Caution symbol and wording "Danger Radioactive Material." The radiation level outside the receptacle should not exceed 1.0 milliroentgens per hour. When full, the bag will be labeled as to content, isotope present, approximate amount of microcuries (or millicuries) and the date. These waste bags will then be collected by personnel of the Radioisotope Branch.

b. All liquid wastes shall be placed in appropriate containers and marked with radioactive caution tape as to isotope content, approximate amounts (in microcuries or millicuries), and the date of collection. This contaminated liquid waste will then be delivered to the Radioisotope Laboratory for disposition.

c. Carcasses of animals containing radioactive material will be marked with radioactive caution tape and delivered to the Radioisotope Laboratory in a container properly marked as to date, isotope content, and approximate amounts in microcuries or millicuries.

d. Fecal material containing radioactive material similarly will be marked with radioactive caution tape, marked as to date, isotopic content, and approximate activity and delivered to the Radioisotope Laboratory.

23. Radioisotope Personnel:

RADIOACTIVE WASTE WILL BE DISPOSED OF ONLY BY PERSONNEL OF THE RADIOISOTOPE LABORATORY

Liquid:

a. Liquids containing short lived radioisotopes will be held in storage until the activity is essentially background. (The material will be stored in such a way that the radiation level outside the storage area will not exceed 1.0 milliroentgen per hour.)

b. All contaminated liquid waste may be disposed of in the "hot" sink provided the quantity which, if diluted by the average daily quantity of sewage (sanitary sewage flow per 24 hours is 525,000 gallons) released into the sewer by the licensee, will not result in an average concentration in excess of values specified in Appendix B, Table I, Column 2 of CFR, Title 10, Part 20; or

c. Ten times the quantity of such material specified in Appendix C of same; and

d. The quantity of any licensed or other radioactive material released in any one month, if diluted by the average monthly quantity of water released by the licensee, will not result in an average concentration exceeding the limits specified in Appendix B, Table I, Column 2 of same; and

e. The gross quantity of licensed and other radioactive material released into the sewage system by the licensee does not exceed one curie per year.

f. All liquid wastes which are held for decay must be placed in appropriate containers and marked as to isotope content, approximate amounts, and the date of collection. The radiation level outside the storage area will not exceed 1.0 milliroentgens per hour.

g. Solid radioactive waste shall be stored in such a way that the radiation level outside the storage area will not exceed 1.0 milliroentgens per hour.

h. All clothing that is known or suspected of being contaminated with a short half-life radioactive isotope or long half-life isotope will be placed in separate container and later destroyed or decontaminated as determined by the Radiation Safety Officer.

i. Disposal of solid radioactive waste will be carried out under the direction of:

Radioactive Material Disposal Facility
U.S. Army Edgewood Arsenal
Edgewood Arsenal, Maryland 21010

Under no circumstances will waste be incinerated.

SECTION VII

DECONTAMINATION OF GLASSWARE

24. All glassware which is utilized directly with radioactive material shall be deemed "contaminated." The decontamination of such glassware is important not only in the interests of radiation safety but also in the unintentional invalidation of additional experimental data.

25. Contaminated glassware will be placed in a "hot" sink where it will be immediately rinsed and then undergo continuous washing. As required, the glassware will be washed in detergent and rinsed in hot water. The wash and rinse cycle will be repeated until three washings have been completed. Washed glassware may be oven or air dried.

26. Pipettes will be rinsed immediately after use and placed in a pipette soaker containing detergent. Washing shall be done by continuous washing in a pipette washer for a minimum of two hours.

27. Syringes shall be disassembled when placed in the sink. As required, syringes will be washed, dried, and monitored before return to central material or put into reuse. When possible the use of disposable syringes and needles is suggested.

28. All glassware which has been decontaminated from gamma radiation will be monitored by an appropriate detector of suitable sensitivity to prevent recontamination during another course of study or experiment. Always monitor after drying, never wet. Decontaminated glassware for low energy beta radiation will be periodically spot checked by the Radioisotope Branch.

29. All glassware which upon monitoring proves to be still contaminated will immediately be placed back into the appropriate washing cycle. If the monitoring again indicates any level of radioactivity, the glassware shall be delivered to the Radioisotope Laboratory for further decontamination.

SECTION VIII

RADIOACTIVE SPILL

30. All radioactive material, when spilled, constitutes a hazard, either to personnel or to equipment. If a spill of radioactive material occurs in Group I (Appendix No. 1) turn off all fans in the immediate area and notify all other personnel in the controlled area. If the spill is liquid, drop absorbent paper on the spill and mark off the area with chalk or cord. If the spill is dry, proceed in the same manner, but convert the dry spill to liquid spill by applying wet absorbent paper over the area.

31. If a spill of radioactive material occurs in Group II (Appendix No. 1), hazard control is of first importance. In order to accomplish this, the person responsible for the spill will:

a. Notify the Radiation Safety Officer or his designated representative.

b. Be prepared to evaluate the hazard by knowing at all times which radioisotope is being handled, its chemical form, and the approximate amount being used (in millicuries or microcuries).

c. See that all personnel in the area are notified and that they leave the immediate area of the spill without delay.

32. In the event of a spill of radioactive material in Group III (Appendix No. 1), the procedure listed above in "a", "b", and "c" should be carried out, plus the following:

a. Determine the extent of personal contamination by inspection and monitoring of the involved personnel.

b. Remove contaminated clothing.

c. Rinse the contaminated body parts with water, if applicable (making use of the sinks located in the area or the emergency shower if the spill took place in the high level room of the Radioisotope Laboratory), and then wash with soap and water, monitoring the contaminated body part after each washing.

33. Decontamination of the area of the spill will be carried out under the supervision of the Radiation Safety Officer, but only after the personnel contamination problem has been disposed of. As a general rule, the work associated with the decontamination is performed by the person responsible for the spill.

34. If ingestion or inhalation is suspected from a spill of radioactive material, AR 40-582 will be complied with, and the following will be accomplished by the Radiation Safety Officer:

a. Evacuate the area of the original contamination.

b. Personal decontamination will be carried out by washing external parts to prevent additional exposure or ingestion.

c. Decontaminate the film badge (when necessary) and forward it by Air Mail Special Delivery to the Lexington Signal Depot; Lexington, Kentucky, with all data concerning the incident (i.e., isotope and its chemical form, amount ingested, date, names, etc.).

d. Carry out all routine decontamination of clothing, work spaces, etc., which were involved.

e. Notify the Surgeon General, Department of the Army, Washington D. C., ATTN: MEDCE-OH, by telegram, of possible internal exposure. Complete DA Form 285 (Accident Report).

f. In the event a very dangerous radioisotope is involved such as H^3, Ca^{45}, Fe^{55}, Sr^{90}, Y91, Zr^{95}, Ce^{144}, Pm^{147}, or Bi^{210} (refer to

AR 40-582), immediately notify the Surgeon General, Department of the Army, Preventive Medicine Division by telephone of:

(1) Time and date of incident
(2) Millicurie strength of isotope and its chemical form.
(3) Name of individual and treatment already undertaken. Include a statement indicating the treatment rendered (or that no treatment has been rendered).
(4) Extent of individual contamination as determined by immediate monitoring.

Telephone notifications will be confirmed by telegraphic notifications.

g. A 24-hour urine sample will be collected under the direction of the Radiation Safety Officer from the person concerned. The collection shall be in a polyethylene liter bottle which will have a card attached containing the following data:

Front:

(1) Name, grade and serial number
(2) Date of incident
(3) Inclusive dates of collection
(4) Isotope and chemical form

Reverse:

A 24-hour urine sample will be collected as follows:

(1) Wash hands before collecting a portion of sample.
(2) Void urine at 0800 hrs (or any other convenient time) and discard it. Do not collect it in the bottle.
(3) Collect all urine from that time up to and including the corresponding hour the following day. ALL URINE MUST BE COLLECTED. LOSS OF A SIGNIFICANT AMOUNT MAY RENDER THE SAMPLE USELESS.

h. Samples will be held until further instructions are received from the Surgeon General. If so directed, forward:

THRU: Commanding General
Walter Reed Army Medical Center
Washington, D. C.

TO: Director
Walter Reed Army Institute of Research
Walter Reed Army Medical Center
Washington, D. C.

ATTN: Department of Biophysics

i. If an overexposure to ionizing radiation occurs, DD Form 1141 (Report of Exposure to Ionizing Radiation) must be completed in accordance with AR 40-431. A brief description of the condition or act which resulted in the overexposure will be attached to the DD Form 1141.

SECTION IX

RADIATION SAFETY MONITORING

35. Area Monitoring:

a. Routine monitoring will be accomplished according to the following time schedule:

Weekly

(1) Radioisotope Laboratory (according to diagram in Appendix 2).

Monthly

(1) USAMRNL (According to diagrams in Appendix 2).

b. Other areas will be monitored when deemed necessary by the Radiation Safety Officer.

c. Readings obtained during the surveys will be recorded and retained as a permanent record.

d. Routine monitoring in USAMRNL (including blowers on roof of Radioisotope Laboratory) will be done, using a portable PAC3G gas proportional counter with a beta detection probe and a GM counter. If contamination is detected, the area will be immediately decontaminated. If any gamma reading, with the GM counter, exceeds a value of 2.0 milliroentgens per hour, the Radiation Safety Officer will be notified. The area will be marked as to reading in milliroentgens/hour and the working time limit.

e. Swipe tests will be routinely conducted and when contamination is suspected. The swipes will be counted in the liquid scintillation counter. Any activity above background will be considered a contaminated area. Readings obtained will be recorded and retained as a permanent record.

f. Any areas of previously undetected contamination will be promptly removed by those persons responsible for the contamination, under the supervision of the Radiation Safety Officer.

36. Personnel Monitoring:

a. Film badges are provided for persons working with radioactive material in USAMRNL. These film badges will be worn during normal working hours and are not to be removed from USAMRNL. Care of the film badge will be the responsibility of the individual user.

b. Badges will be collected monthly by the Radioisotope Laboratory personnel. The collected badges will be sent to Lexington Signal Depot, Lexington, Kentucky for processing and reading. The returned values will be permanently recorded in Radioisotope Branch files on AEC Form Nos. 4 and 5 and DD Form 1141.

c. A thorough medical examination should be made of each individual potentially exposed to significant amounts of radiation before employment and annually thereafter.

d. Those persons working with millicurie amounts of Tritium shall have periodic urine checks for radioactivity.

SECTION X

LOGS AND RECORDS

37. AEC Form 3 (Notice to Employees - Standards for Protection

Against Radiation) will be posted in a conspicuous location.

38. AEC Forms 4 and 5 (History of Exposure and Record of Exposure to Ionizing Radiation) will be kept. This record will also be entered on DD Form 1141 in accordance with AR 40-431.

39. The USAMRNL SOP will be posted and the AEC licenses will be readily available.

40. Radioisotope inventory balance will be determined monthly. (Radioisotope inventory records are kept on Forms DA 8-235 and DA 8-212).

41. Instrument logs will be maintained indicating calibration and maintenance of the portable survey instruments.

42. Records of surveys (including wipe tests) will be kept.

43. Caution signs, labels, and signals will be utilized according to CFR, Title 10, Part 20, para. 20.203.

44. A report covering the period of each calender quarter will be prepared by the Commander of Fitzsimons General Hospital in accordance with AR 40-37. This report will be dispatched to the Surgeon General, ATTN: MEDPS-PO, by the fifteenth working day following the close of the report period and will contain the following information as a minimum:

a. Copy of minutes of each Radioisotope Committee meeting, including a record of all actions taken by the Committee.

b. Copy of the training and experience of each newly approved user of radioisotopes or any change in qualifications or certifications of previously approved user (for human use, AEC Form 313a, page 3).

c. Radioisotope inventory, including data on quantities of radioisotopes procured, used, or disposed of, or currently in storage.

d. List of procedures with dosage for each radioisotope used in humans during the reporting period.

e. Information on unsolved problems, new or improved developments, or other comments of interest to, or having a bearing on, support rendered by the Surgeon General.

f. Notification of all changes in membership of Radioisotope Committee.

SECTION XI

OTHER ROUTINE LABORATORY PROCEDURES

45. Neatness in the laboratory is a prime requisite for elimination of the spread of contamination. The work area should be free of equipment and materials not required for the experiment at hand, and equipment used will be decontaminated and stored in a controlled location after use.

46. Floors in the Radioisotope Laboratory should be cleaned frequently by wet mopping. Brooms and mops will not be transferred to other area unless they are free from radioactive contamination.

47. Table tops, equipment, or any surface within the Radioisotope Laboratory will be kept clean. Under no circumstances will there be an accumulation of dust and/or possible contamination.

48. Floors will be waxed and buffed on a monthly basis.

49. Air conditioner filters, glove box filters, and hood filters will be checked quarterly and properly cleaned or replaced when necessary.

50. Desiccant in the liquid scintillation counter will be checked weekly and changed when necessary.

51. The emergency shower will be checked weekly.

52. The survey meters will be calibrated at least every six months and after every maintenance procedure or battery change.

53. Batteries in the survey meters will be checked monthly, and changed when necessary.

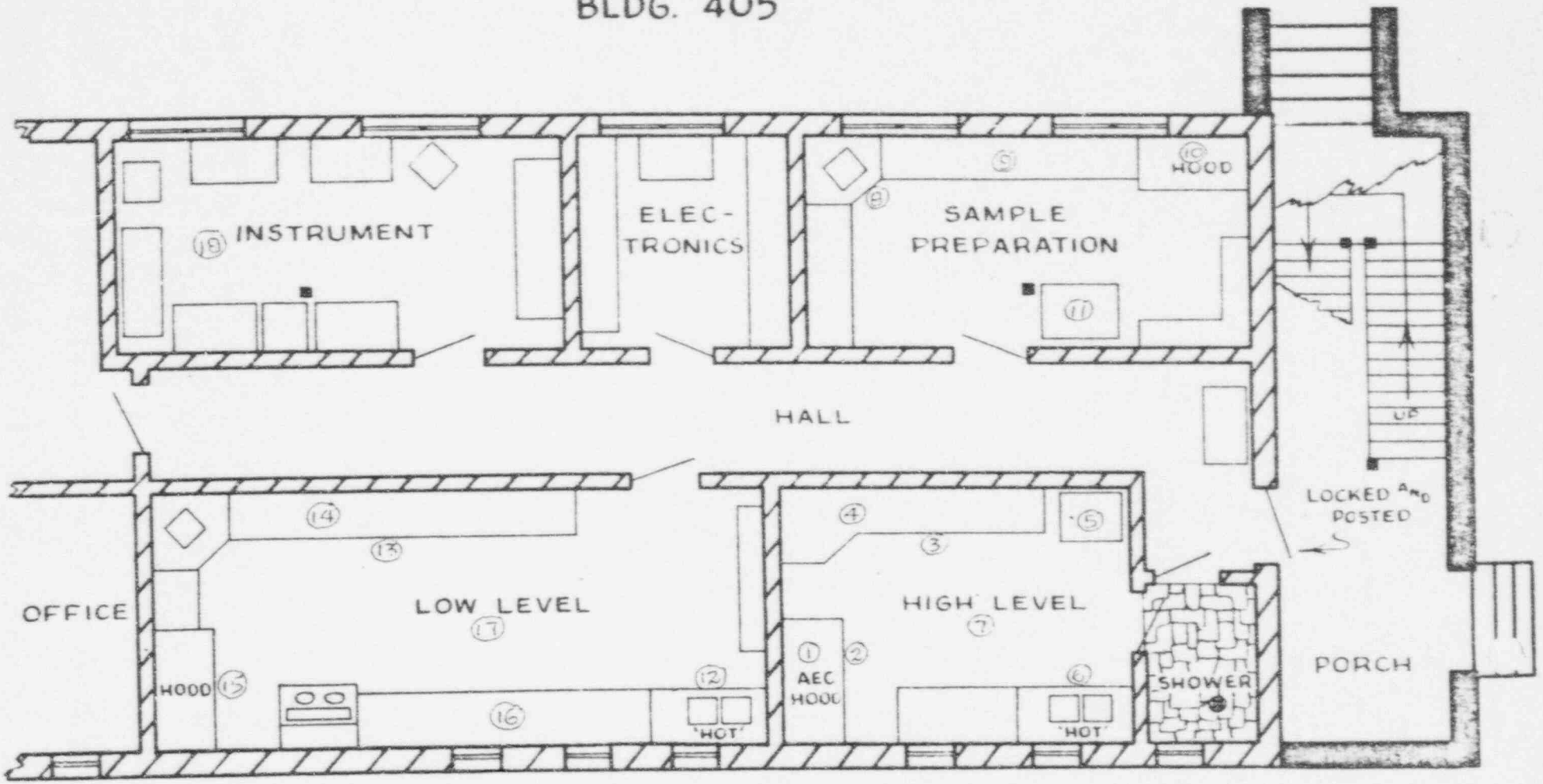
Safe Handling Level For Some Representative Radioisotopes
Authorized For Use In USAMRNL

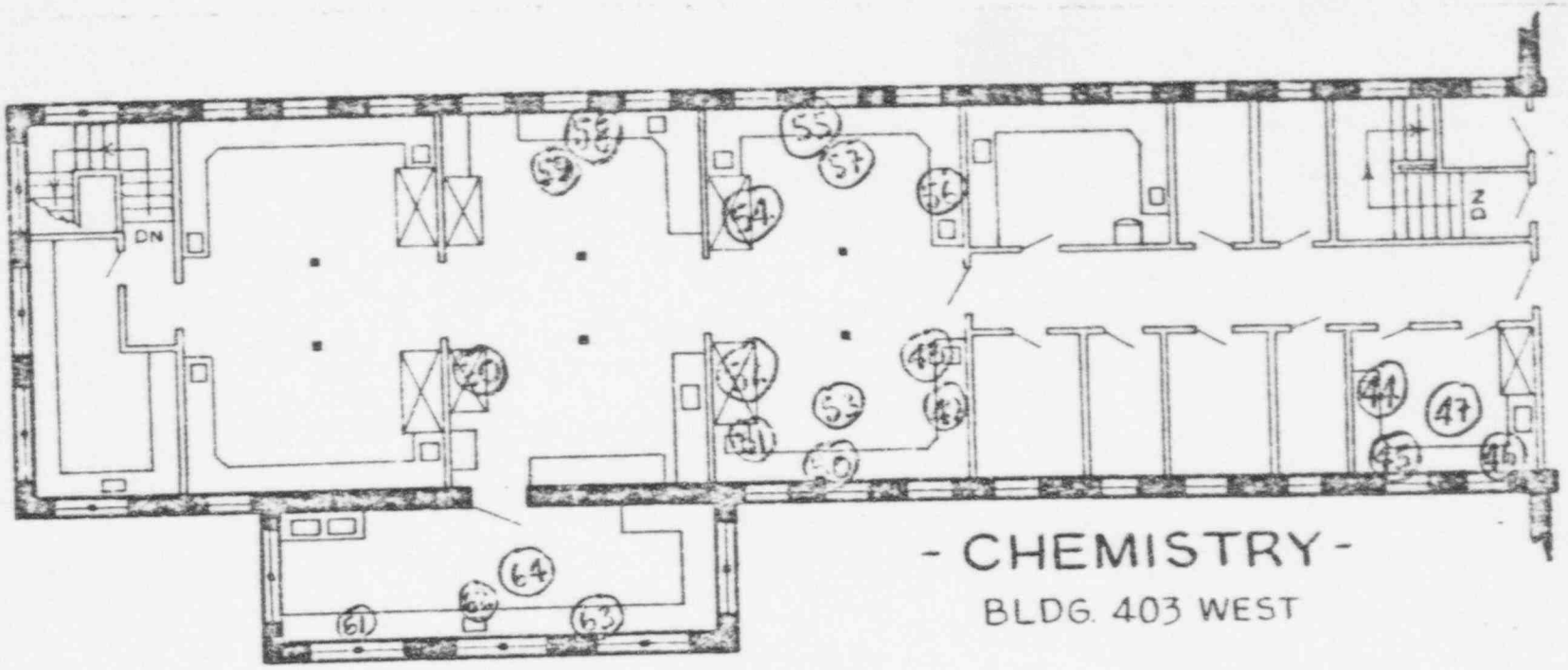
GROUP I **No special handling required in normal laboratory procedures		GROUP II **Not dangerous, but unnecessary exposure is to be avoided		GROUP III **Dangerous, should be handled with utmost caution		
Isotope	Maximum Amount	Isotope	Maximum Amount	Isotope		Amount
Au^{198}	0.025mc	Au^{198}	1.000mc	Au^{198}	over	1.000mc
Br^{82}	0.300mc	Br^{82}	5.000mc	Br^{82}	"	5.000mc
Be^{7}	0.005mc	Be^{7}	0.100mc	Be^{7}	"	0.100mc
*C^{14} Urea	0.050mc	C^{14} Urea	1.000mc	C^{14} Urea	"	1.000mc
*C^{14} all other	0.025mc	C^{14} all other	1.000mc	C^{14} other	"	1.000mc
Ca^{45}	0.005mc	Ca^{45}	0.100mc	Ca^{45}	"	0.100mc
Co^{60}	0.025mc	Co^{60}	1.000mc	Co^{60}	"	1.000mc
Cr^{51}	0.025mc	Cr^{51}	1.000mc	Cr^{51}	"	1.000mc
Fe^{55}	0.005mc	Fe^{55}	0.100mc	Fe^{55}	"	0.100mc
Fe^{59}	0.025mc	Fe^{59}	1.000mc	Fe^{59}	"	1.000mc
*H^{3} Water	0.025mc	H^{3} Water	10.000mc	H^{3} Water	"	10.000mc
*H^{3} Thymidine	0.001mc	H^{3} Thymidine	0.050mc	H^{3} Thymidine	"	0.050mc
*H^{3} all other	0.005mc	H^{3} all other	0.100mc	H^{3} other	"	0.100mc
I^{131}	0.025mc	I^{131}	1.000mc	I^{131}	"	1.000mc
Na^{22}	0.025mc	Na^{22}	1.000mc	Na^{22}	"	1.000mc
P^{32}	0.025mc	P^{32}	1.000mc	P^{32}	"	1.000mc
S^{35}	0.025mc	S^{35}	1.000mc	S^{35}	"	1.000mc
Se^{75}	0.025mc	Se^{75}	1.000mc	Se^{75}	"	1.000mc
Sr^{85}	0.025mc	Sr^{85}	1.000mc	Sr^{85}	"	1.000mc
Sr^{89}	0.025mc	Sr^{89}	1.000mc	Sr^{89}	"	1.000mc
Sr^{90}	0.005mc	Sr^{90}	0.100mc	Sr^{90}	"	0.100mc
Zn^{65}	0.005mc	Zn^{65}	0.100mc	Zn^{65}	"	0.100mc

* Group classification dependent upon chemical form.

**It must be remembered that these limits are by no means fixed and that any undue exposure is undesirable. Therefore, when working with the above radioisotopes, the physical characteristics, half-life, the internal and external hazard, and the radiative properties of the radioactive material must be considered. If in doubt, always consult the Chief, Radioisotope Branch.

RADIOISOTOPE LABORATORY
USAMRNL
BLDG. 405

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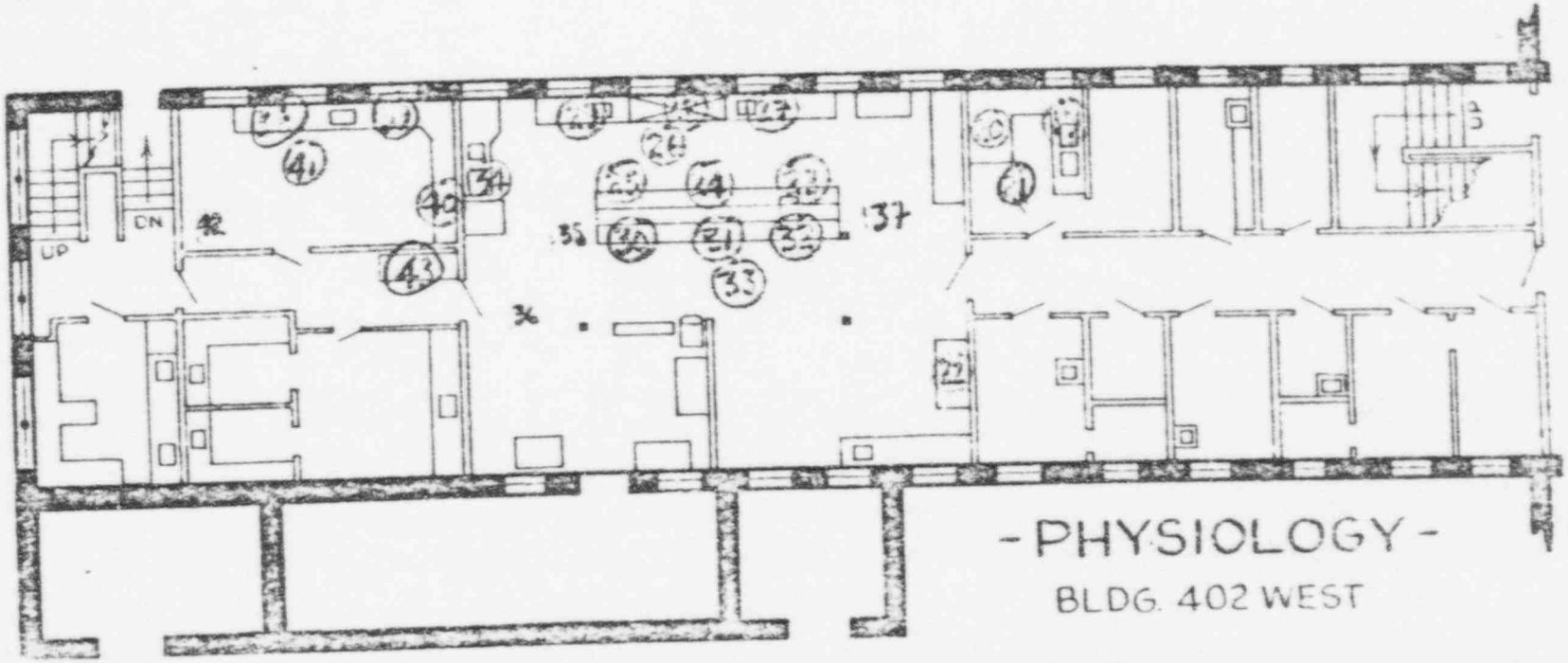
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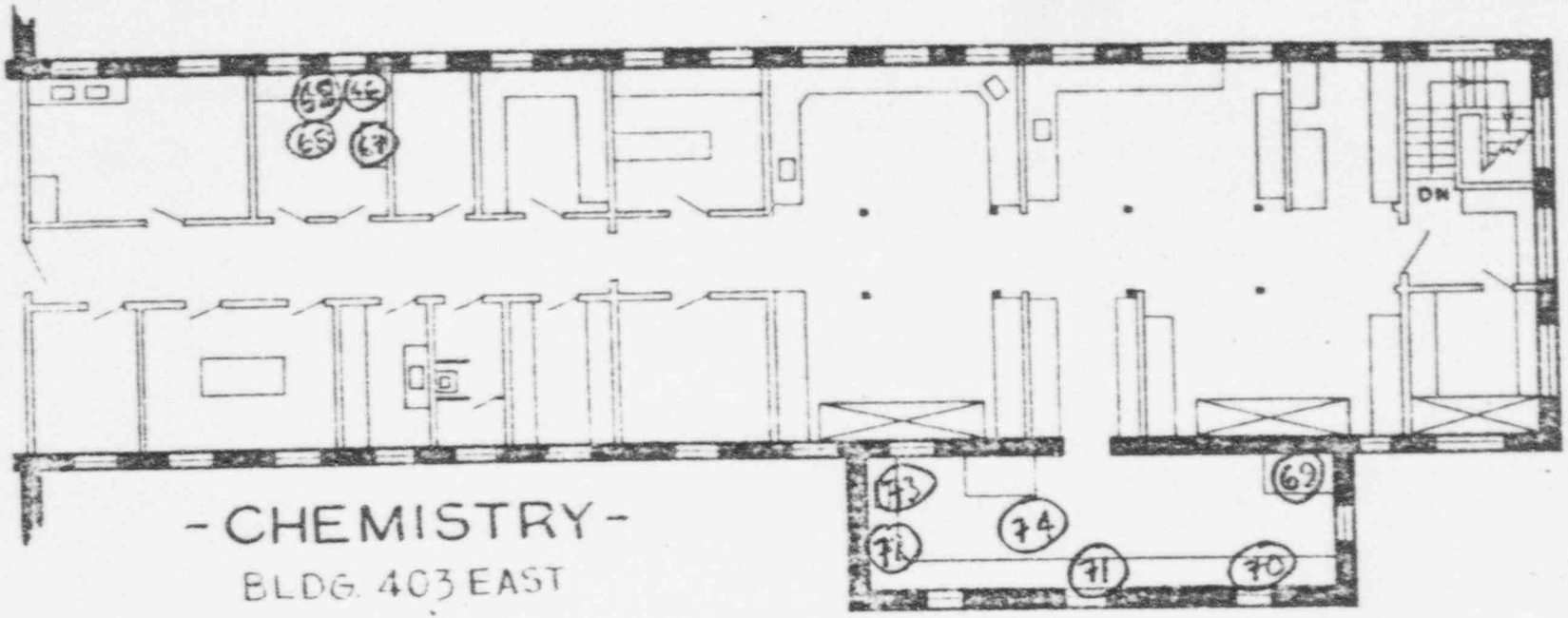

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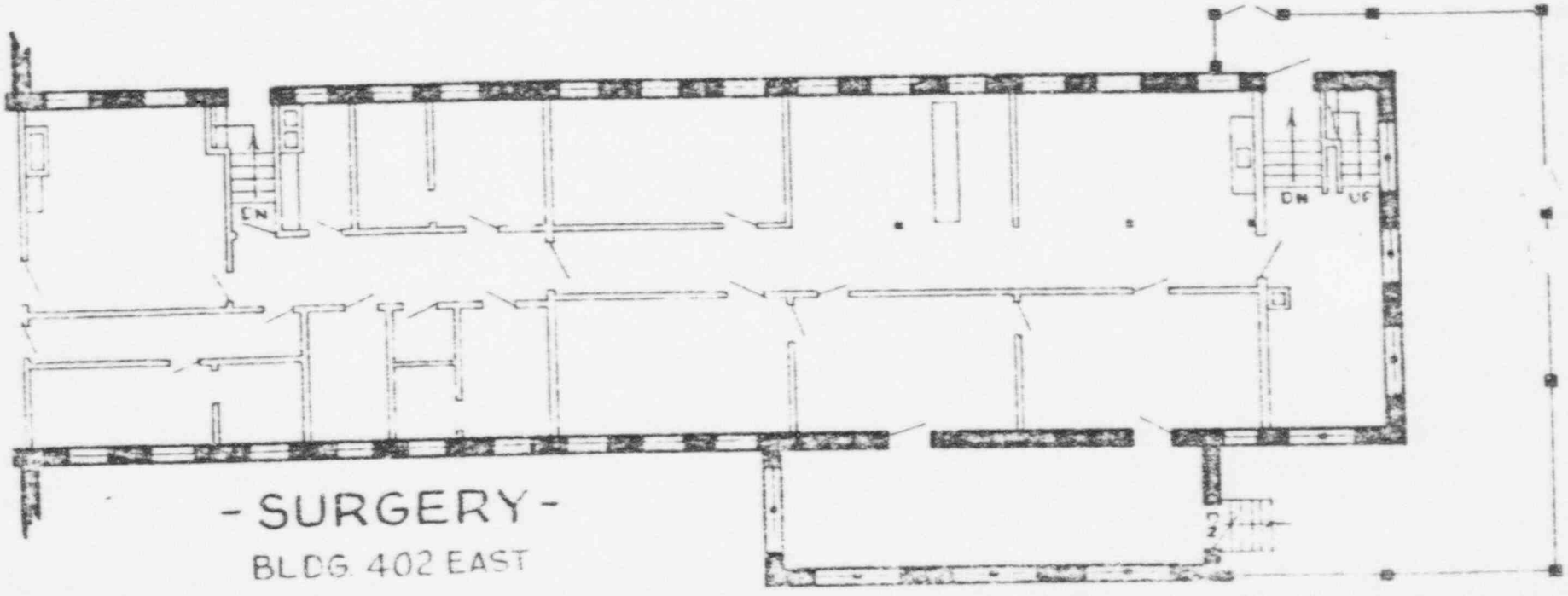

- SURGERY -

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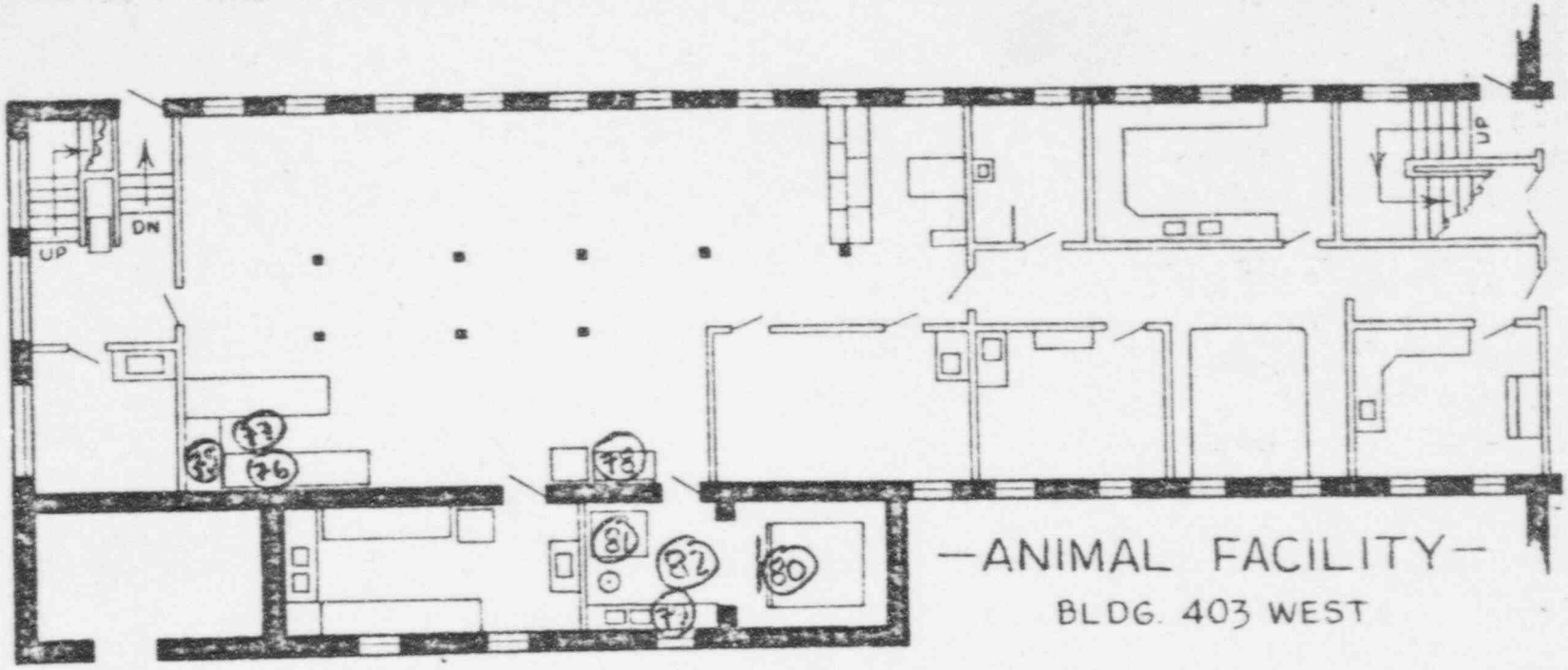

—ANIMAL FACILITY—

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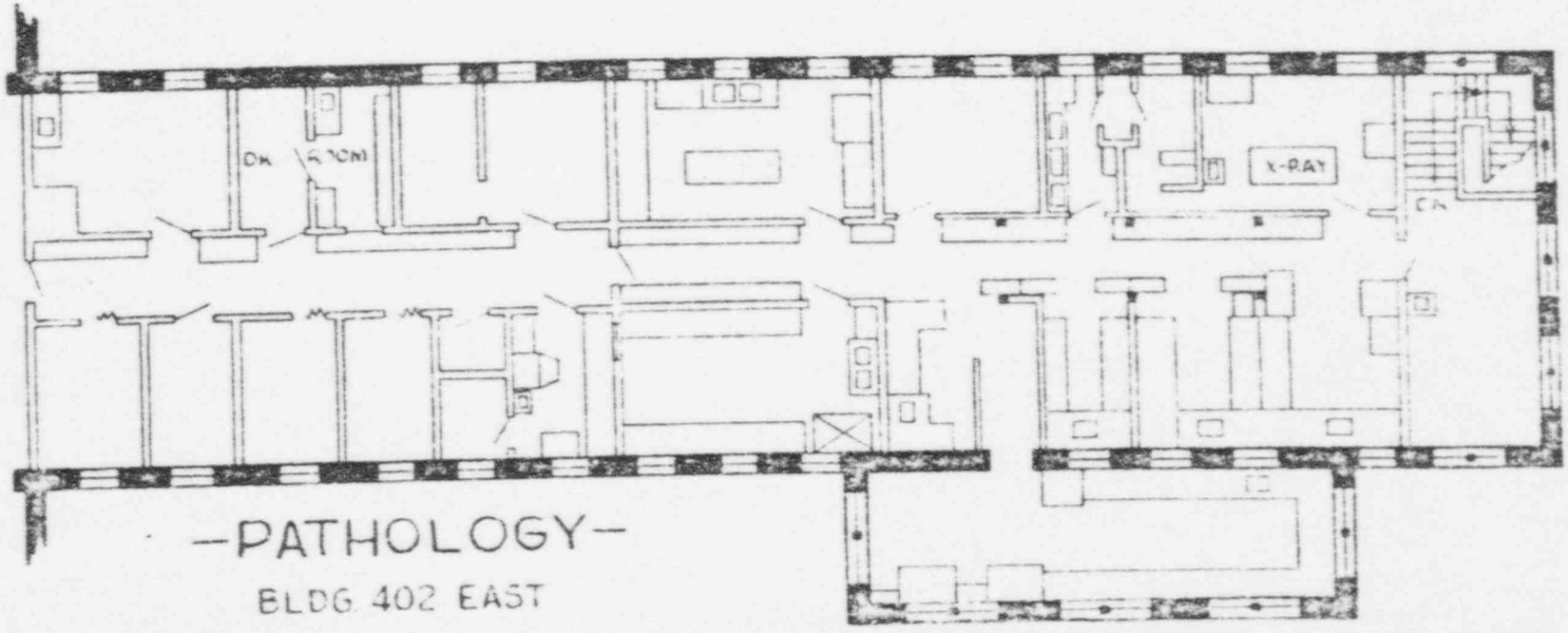

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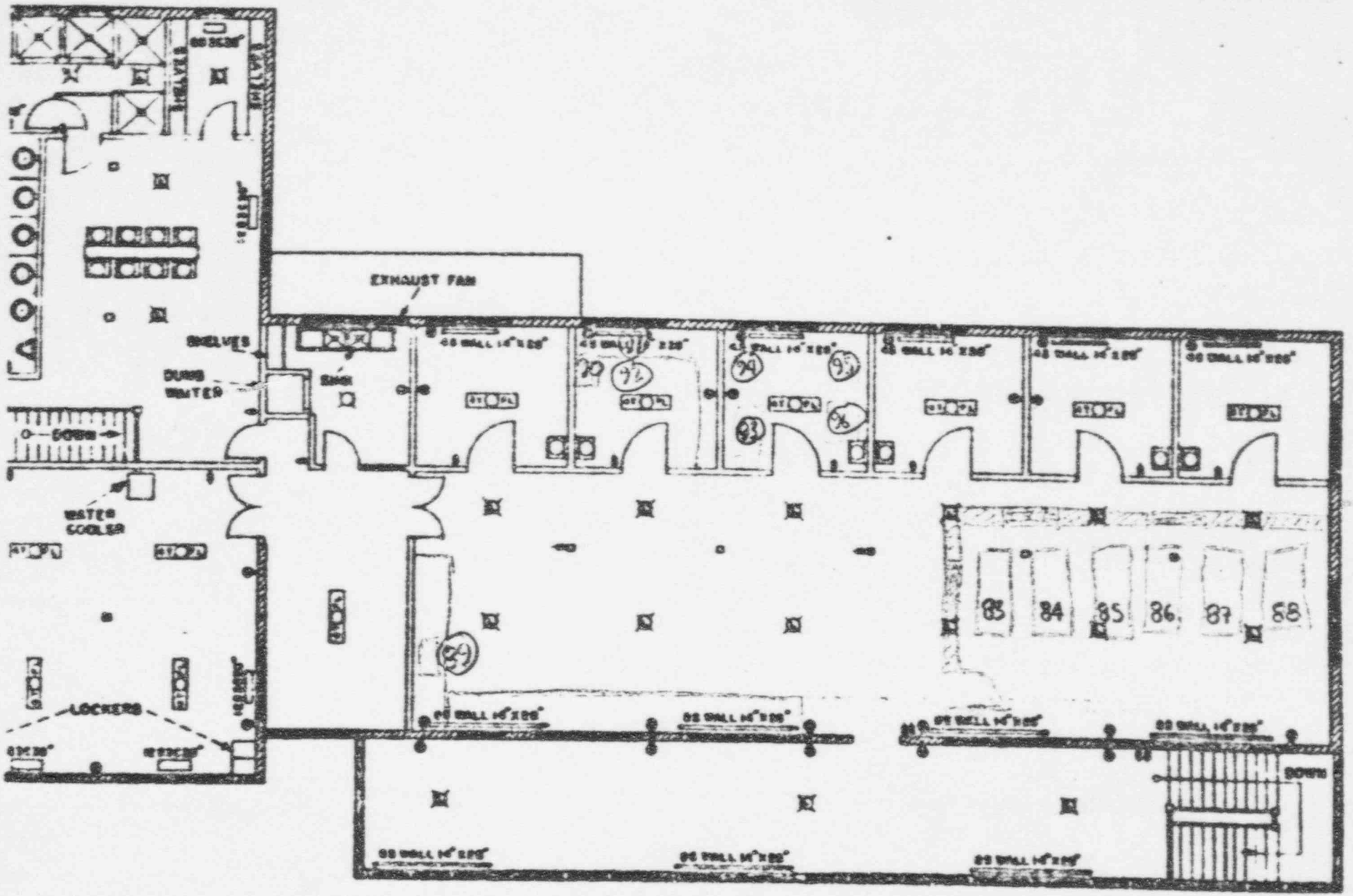
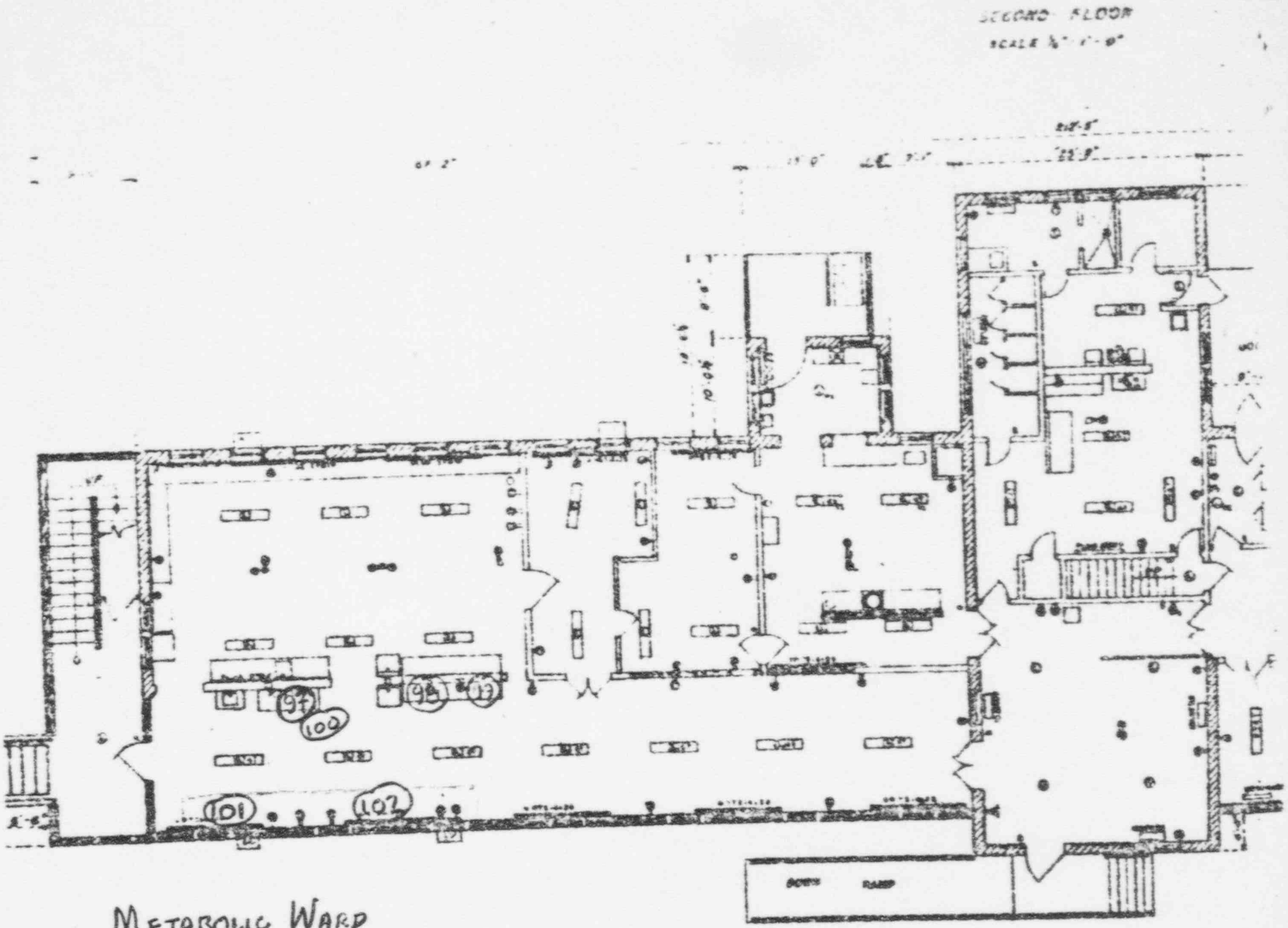


2ND FLOOR- EAST 600



METABOLIC WARD
1ST FLOOR WEST

APPENDIX F

RADIOACTIVE WASTE TREATMENT AT THE U.S. ARMY MEDICAL RESEARCH AND NUTRITION LABORATORY

I. SOURCES: Biological and metabolic experiments using primarily animals and occasionally humans.

II. COLLECTION:

A. Responsibility for collecting waste, rests with each investigator.

B. Methods for the collection of radioactive waste are the following:

1. Each sector dealing with radioactive material has radioactive waste receptacles with waxed bag inserts for collection of waste material. These are collected periodically and placed in polyethylene bags.

2. Solids are placed in polyethylene bags.

3. Liquids are sealed in glass bottles.

4. Animal carcasses and tissues are put in polyethylene bags and frozen immediately.

5. All radioactive waste is brought to the Radioisotope Section for disposal. Each package is labeled as follows:

a. Isotope

b. Activity in microcuries

c. Material, e.g. glass, paper

d. Date

e. Investigator's name

6. Also, each package has affixed to it, radioactive tape with the warning "Caution Radioactive Material."

C. Local handling is carried out in the following manner:

1. Non-combustible and combustible waste is segregated into fifty-five gallon drums and sealed. These are stored in the outside freezer located north of Building 602, West Wing.

2. Animal carcasses and tissues are sealed in fifty-five gallon drums and stored in the outside freezer.

3. Animal carcasses from studies conducted in the Small Animal Room may be stored in polyethylene bags in the Small Animal Room freezer. When gamma-emitters are used, the freezer is monitored once a week; otherwise, monitoring is performed once a month.

4. Edgewood Arsenal is notified that there is waste to be disposed of with a listing of the approximate amount of activity and the type of waste material that has accumulated.

5. A disposition date is obtained from Edgewood Arsenal.

6. If an escort from Edgewood Arsenal is not available to pick up the waste then the Radioisotope Section arranges with the Transportation Office to provide local carriers to ship the waste.

III. PACKAGING

A. Wastes are sorted on the basis of:

1. Combustibility vs. non-combustibility of the material involved.

2. The type of isotope and the activity contained within the package.

B. Packaging practices followed are:

1. Solids are placed in two polyethylene bags, one enclosed in the other.

2. Liquids are stored in large glass bottles until disposition. After sewage disposal glass containers are treated as non-combustible radioactive waste.

C. Shielding is carried out as follows:

1. No special shielding for beta-emitters up to the millicurie range is required.

2. Storing gamma-emitters in the outside freezer provides shielding and distance for laboratory personnel.

3. The high-level non-perishables are stored behind lead bricks in a room that is separated from the main working area.

D. The only local waste treatment performed is the disposal of liquid waste into the sanitary sewage system.

1. Where the amounts of the isotope to be disposed are less than the amount allowed in paragraph 20.303 and Appendix C of Title 10 of AEC Regulations, then the radioactive waste may be flushed into the sewage system with copious amounts of water.

2. The disposal is scheduled so that the sewage from USAMRNL, as well as that of the Radioisotope Clinic, FGH, will not exceed the total amount allowed. This is accomplished by scheduling specific days for each laboratory to dispose of its waste.

3. All liquid disposal at USAMRNL is accomplished in the sink located in the High Level Laboratory.

E. Solid wastes are disposed of by packaging in fifty-five gallon drums sealed air tight, and stored in the outside freezer until enough waste is collected to justify a shipment.

F. The procedures of the U.S. Army Nuclear Defense Laboratories are followed to facilitate interstate transportation by a local carrier to Edgewood Arsenal.

IV. STORAGE

A. Storage is provided by an outside freezer maintained at temperatures below 0° F and by a lead-lined hood in the High Level Laboratory. Both places are adequately sealed and are designated as "Radiation Areas."

B. The combustible and non-combustible beta-emitters and low activity gamma-emitters are stored in the outside freezer.

C. In the event that high activity wastes should occur, then the perishables, e.g. animal carcasses, are stored in the outside freezer, while the non-perishables are stored in the High Level Laboratory.

D. Local storage space is sufficient to accommodate approximately

fifteen fifty-five gallon drums. This amount may be collected during a three-month period prior to shipment.

V. SHIPPING

A. Ten to fifteen fifty-five gallon drums are shipped approximately every three months.

B. The waste is shipped via refrigerated trucks obtained from Edgewood Arsenal or by local carrier.

C. Release through local environment is accomplished only by discharging liquid waste as described under "Packaging." There is no incineration or burial of waste materials.

VI. MONITORING

A. Drums are monitored to provide readings at the surface of the drums.

B. Swipe tests are performed on the surface of the drums to assure that no incidental contamination has occurred.

C. The following safeguards are taken:

1. Animals stored in the freezer in the Small Animal Room are monitored weekly if gamma-emitters are present; monthly, if only beta-emitters are present.

2. The outside freezer is monitored weekly.

3. High level material stored in the High Level Laboratory is monitored weekly.

VII. AUTHORITY

A. U.S. Atomic Energy Commission Byproduct Material License No. 5-46-13.

B. Atomic Energy Commission Rules and Regulations, Title 10, Part 20.

C. Army Regulation No. 55-55.

D. Title 49, Parts 71-78, Code of Federal Regulations, Transportation.

E. Department of the Army Circular No. 385-4.

F. Procedures for Use of Radioactive Material, USAMRNL, Fitzsimons General Hospital.

APPENDIX G

REQUEST FOR APPROVAL FOR USE OF RADIOISOTOPES AT THE SUMMIT OF PIKES PEAK, COLORADO

Request approval for the use of Chromium-51, Hydrogen-3, Sulfur-35, and Bromine-82 in the amounts specified (part 6, Form AEC-313, TT through WW) for metabolic studies in lower animals at the summit of Pikes Peak, Colorado. Previous approval has been granted for the use of Iodine-131 and Iodine-125 for metabolic studies in lower animals (amendment number 3, dated 12 August 1964 and amendment number 4 received 4 June 1965). Permission is only requested to use a protion of our present authorization at the summit of Pikes Peak, Colorado, thus the quantities (millicuries) requested are not in addition to those already authorized.

Experiments involving radioisotopes will follow procedures set forth by the Radioisotope Committee, USAMRNL. Determinations involving isotopes will be conducted in the USAMRNL Field Laboratory trailer at Pikes Peak, Colorado. All isotope materials will be transported in government vehicles to the labroatory site in plastic containers which, in turn, will be returned in like manner. Transportation of radioactive materials will be carried out in accordance with AR 55-55. All radioactive samples from the animals will be transported to the Denver Laboratory by government vehicle in lead containers for analysis.

All waste materials, including urine, feces, glassware, syringes and needles etc. will be returned to Denver under similar precautions. No labeled or contaminated material of any kind will be disposed of at Pikes Peak. Animal cages, glassware and other equipment coming into contact with radioactive material will be decontaminated at the Denver Laboratory. Stainless steel metabolism cages will be utilized so the complete urine and fecal collections can be made and disposed of as described.

The experimental area at Pikes Peak will be continuously monitored with an end-window detector and rate meter (Labitron, Nuclear Chicago, Model 1619A). Area surveys and transportation of materials will be monitored with a portable survey meter (Nuclear Chicago, Model 2612), and area swipes will be taken for liquid scintillation counting (Packard, Model 3314) for tritium.

Continuation of Item 10 APPENDIX H 21 June 1966

TYPE OF INSTRUMENTS	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm^2)	USE
3. Nuclear Chicago Mod. 4351 Tobar Gamma Countin g System	1	Gamma	N/A	N/A	measuring
4. Beckman Low Beta II	1	Alpha, Beta	N/A	80 ug/cm^2	measuring
5. Eberline Mod. PAC 3G with Beta Probe	1	Beta	N/A	0.85 mg/cm^2	surveying