

MEDDH-RM

6 April 1964

Lt. Colonel Marion E. McDowell, MC  
Commanding  
U.S. Army Medical Research and Nutrition Laboratory  
Fitzsimons General Hospital  
Denver, Colorado, 80240

Dear Mac:

For what it may be worth, Preventive Medicine Division has requested  
AEC to approve the use of isotopes away from MRNL and FGH.

Sincerely,

1 Incl  
Ltr dtd 27 Mar 64

IRVIN C. PLOUGH  
Lt. Colonel, MC  
Chief, Medical  
Research Branch

ICP/rb

WNRC : 12 Dec 94  
RG : 112  
Accession # 69A-0128  
Box : 40  
File Name: Request For  
Approval For Human Use  
of Radioisotopes in Tracer  
Amounts in Volunteer Exp.  
Research Subjects.

# APPLICATION FOR BYPRODUCT MATERIAL LICENSE

**INSTRUCTIONS.** - Complete Items 1 through 16 if this is an initial application. If application is for renewal of a license, complete Items 1 through 7 and indicate new information or changes in the program as requested in Items 8 through 15. Use separate 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. NAME AND STREET ADDRESS OF APPLICANT (Institution, firm, hospital, etc.)  
Department of the Army  
Fitzsimons General Hospital and USAMRNL  
Denver, Colorado 80210

(b) STREET ADDRESS(S) AT WHICH BYPRODUCT MATERIAL WILL BE USED (If different from 1 (a))  
Installation named in 1 (a); other installations at which research studies may be conducted under the supervision of Fitzsimons General Hospital with the prior approval of the AEC and SGO

2. DEPARTMENT TO USE BYPRODUCT MATERIAL  
Biological Service  
USAMRNL

3. PREVIOUS LICENSE NUMBER(S) (If this is an application for renewal of a license, please indicate and give number)  
Renew and combine 5-46-7, 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)  
Approved by the Radioisotope Committee, AEC-313a Page 3 and Curriculum and submitted

5. RADIATION PROTECTION OFFICER (Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience in Items 8 and 9)  
Appointed by the Radioisotope Committee. Training and experience submitted.

6. (a) BYPRODUCT MATERIAL (Element and mass number of each)  
Byproduct material with Atomic nos. 1 to 10 inclusive for animal and in vitro use of byproduct material for animal use as itemized in enclosure.

(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)  
Maximum total amount on hand 10 curies.  
Tritium 5 curies  
Xenon 2 curies  
Any other byproduct material 500 millicuries  
Refer to enclosure.

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 as part 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 the name of the source. It be stored and/or used.)

Animal and in vitro research  
Reference - A.E.C. 313a

**U. S. ATOMIC ENERGY COMMISSION  
BYPRODUCT MATERIAL LICENSE**

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Part 30, Licensing of Byproduct Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below; and to use such byproduct material for the purpose(s) and at the place(s) specified below. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, and is subject to all applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

<b>Licensee</b>		
Name	Department of the Army Fitzsimons General Hospital and	3. License number 5-46-13 (A55)
Address	U.S. Army Medical Research and Nutrition Laboratory Denver, Colorado	4. Expiration date January 31, 1966
		5. Reference No.

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
A. Iodine 131 B. Iodine 131 (See page 2)	A. Iodide B. Iodinated Human Serum Albumin	A. 250 millicuries B. 5 millicuries

**Authorized use**

- Diagnosis of thyroid function and thyroid scanning. Treatment of hyperthyroidism, cardiac conditions and thyroid carcinoma.
  - Determination of plasma volumes and cardiac output. Cardiac scanning. Localization of brain tumors. Performance of placentograms.
- (See page 2)

**CONDITIONS**

Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2 above. ✓

The licensee shall comply with the provisions of Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards For Protection Against Radiation."

- 12. Byproduct material shall be used by, or under the supervision of, individuals designated by the Fitzsimons General Hospital and U.S. Army Medical Research and Nutrition Laboratory Radioisotope Committee.
- 13. Byproduct material shall not be used in humans until its pharmaceutical quality and assay have been established.
- 14. Each sealed source containing byproduct material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made six months prior to the transfer, the sealed source shall not be put into use until tested.

(Continued)

U. S. ATOMIC ENERGY COMMISSION  
BYPRODUCT MATERIAL LICENSE  
Supplementary Sheet

License Number 5-46-13  
(A66)

Continued

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radio- activity which licensee may possess at any one time
C. Iodine 131	C. Hippuric acid	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. Cholografin	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. Hippuric acid	K. 1 millicurie
L. Iodine 125	L. Rose Bengal	L. 1 millicurie
M. Iodine 125	M. Triolein 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. 250 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 except Hydrogen 3 - 5 curies. Total not to exceed 10 curies

**U. S. ATOMIC ENERGY COMMISSION  
BYPRODUCT MATERIAL LICENSE  
Supplementary Sheet**

License Number 5-46-13  
(A66)

Authorized use continued

- D. Determination of renal function.
- J. 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.
- PB. Determination of pulmonary function.  
Bone scanning.
- AD. Treatment of superficial eye conditions.  
Laboratory research in vitro and in lower animals.

Condition 14 continued

The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

(See page 4)

U. S. ATOMIC ENERGY COMMISSION  
BYPRODUCT MATERIAL LICENSE  
Supplementary Sheet

License Number 5-46-13  
(A66)

Condition 14 continued

- 14. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five days of the test with the Director, Division of Licensing and Regulation, U.S. Atomic Energy Commission, Washington 25, D. C., describing the equipment involved, the test results and the corrective action taken. A copy of such report shall also be sent to the Director, Region IV, Division of Compliance, USAEC, P. O. Box 15266, Denver 15, Colorado.
- 15. Byproduct material designated in Items 6.EE., 7.EE., and 8.EE. shall not be used in humans.
- 16. Except as specifically provided otherwise by this license, the licensee shall possess and use byproduct material described in Items 6, 7 and 8 of this license in accordance with statements, representations and procedures contained in application dated December 6, 1963.

For the U. S. Atomic Energy Commission

by [Signature]  
Isotopes Branch

Division of Licensing and Regulation  
Washington 25, D. C.

MEDDH-RM (19 Dec 63)

1st Ind

SUBJECT: Request for Approval to Use Radioisotope Tracers in Volunteers

HQ, US Army Medical R&D Command, DA, OTSG, Washington, D.C. 20315 MAR 2

TO: Commanding Officer, U.S. Army Medical Research and Nutrition  
Laboratory, Fitzsimons General Hospital, ATTN: MEDEN-CO, Denver,  
Colorado 80240

Subject request is granted approval per the attached memo from the  
Secretary of the Army.

1 Incl  
wd 1 incl  
Added 1 incl

*Robert E. Blount*  
for  
ROBERT E. BLOUNT  
Brigadier General, MC  
Commanding

*Incl #1*



IN REPLY REFER TO:

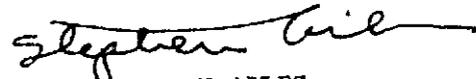
DEPARTMENT OF THE ARMY  
WASHINGTON 25, D.C.

FEB 22 1964

MEMORANDUM FOR: CHIEF OF STAFF, UNITED STATES ARMY

SUBJECT: Request for Approval to Use Radioisotope Tracers  
in Volunteers

Approval is granted for the use of radioactive isotopes as tracers in volunteer human subjects of research in conformance with the protocol submitted to The Surgeon General, by letter MEDEN-CO, U. S. Army Medical Research and Nutrition Laboratory, Fitzsimons General Hospital, Denver, Colorado, subject as above, dated 19 December 1963.

  
STEPHEN AILES  
Secretary of the Army

U. S. ARMY MEDICAL RESEARCH AND NUTRITION LABORATORY

FITZSIMONS GENERAL HOSPITAL

DENVER 16, COLORADO 80240

IN REPLY REFER TO:

ME DEN-CO

19 December 1963

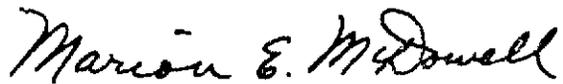
SUBJECT: Request for Approval to Use Radioisotope Tracers in Volunteers

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

1. Enclosed are copies of a Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects.

2. Eight copies of the request are furnished to facilitate early processing, however, only three copies are provided with Appendix IV, "Reprints Supporting Vitamin C Studies," due to a short supply.

1 Incl  
a/s (8 copies)



MARION E. McDOWELL  
Lt Colonel, MC  
Commanding

MEDPS-PC

27 March 1964

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

Gentlemen:

Recommend approval of the inclosed application for amendment to AEC Byproduct Material License No. 5-46-13 (A66) for Fitzsimons General Hospital and the U. S. Army Medical Research and Nutrition Laboratory, Denver, Colorado.

Your attention is invited to condition 10 of AEC Byproduct Material License No. 5-46-13 dated 3 February 1964. It is requested that this condition be amended so that use of radioisotopes in tracer amounts for human volunteers be authorized for use at those places which have been approved as a part of an authorized study by the Radioisotope Committee of Fitzsimons General Hospital and the U. S. Army Medical Research and Nutrition Laboratory, The Surgeon General, and the Secretary of the Army in accordance with statements of application dated 12 March 1964.

Sincerely yours,

1 Incl  
AEC-313 (in trip)

ROSWELL G. DANIELS  
Lt Colonel, MC  
Preventive Medicine Division

ATOMIC ENERGY COMMISSION  
**APPLICATION FOR BYPRODUCT MATERIAL LICENSE**

**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.

<p>1. (a) NAME AND STREET ADDRESS OF APPLICANT. (Institution, firm, hospital, person, etc.) <b>Department of the Army, Fitzsimons General Hospital and U. S. Army Medical Research and Nutrition Laboratory Denver, Colorado</b></p>	<p>(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. (If different from 1 (a)) <b>Installations named in 1 (a) and, for Carbon-14, those locations named in Paragraph 6, d(2) pages 19 &amp; 20 (and subject to conditions therein specified) of approved Incl # 2, "Request for Approval (continued Supplement A)</b></p>
<p>2. DEPARTMENT TO USE BYPRODUCT MATERIAL <b>Radiology Service, FGH, and USA Med Resch &amp; Nutr Lab</b></p>	<p>3. PREVIOUS LICENSE NUMBER(S). (If this is an application for renewal of a license, please indicate and give number.) <b>License No. 5-46-13 (A66) with expiration date January 31, 1966</b></p>
<p>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.) <b>As specified in License No. 5-46-13(A66) condition 12</b></p>	<p>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.) <b>As specified in application (dtd Dec 6, '63) for License No. 5-46-13(A66)</b></p>

<p>6 (a) BYPRODUCT MATERIAL. (Elements and mass number of each) <b>A. Carbon-14 B. Carbon-14 C. Carbon-14 D. Carbon-14 E. Carbon-14 F. Carbon-14 G. Carbon-14 H. Hydrogen-3 I. Magnesium-28 J. Calcium-47 K. Calcium-45</b></p>	<p>(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, sources and maximum activity per source.)</p> <table border="0"> <tr><td><b>A. Vitamins</b></td><td><b>A. 10 mc</b></td></tr> <tr><td><b>B. Amino Acids</b></td><td><b>B. 10 mc</b></td></tr> <tr><td><b>C. Lipids (as glycerides, cholesterol &amp; free fatty acids)</b></td><td><b>C. 10 mc</b></td></tr> <tr><td><b>D. Acetate</b></td><td><b>D. 10 mc</b></td></tr> <tr><td><b>E. Carbohydrates</b></td><td><b>E. 10 mc</b></td></tr> <tr><td><b>F. Mevalonic acid</b></td><td><b>F. 10 mc</b></td></tr> <tr><td><b>G. Bicarbonate, CO<sub>2</sub></b></td><td><b>G. 10 mc</b></td></tr> <tr><td><b>H. Vitamins</b></td><td><b>H. 50 mc</b></td></tr> <tr><td><b>I. MgO, Mg Cl<sub>2</sub>, Mg citrate</b></td><td><b>I. 10 mc</b></td></tr> <tr><td><b>J. Ca Cl<sub>2</sub></b></td><td><b>J. 10 mc</b></td></tr> <tr><td><b>K. Ca Cl<sub>2</sub></b></td><td><b>K. 10 mc</b></td></tr> </table>	<b>A. Vitamins</b>	<b>A. 10 mc</b>	<b>B. Amino Acids</b>	<b>B. 10 mc</b>	<b>C. Lipids (as glycerides, cholesterol &amp; free fatty acids)</b>	<b>C. 10 mc</b>	<b>D. Acetate</b>	<b>D. 10 mc</b>	<b>E. Carbohydrates</b>	<b>E. 10 mc</b>	<b>F. Mevalonic acid</b>	<b>F. 10 mc</b>	<b>G. Bicarbonate, CO<sub>2</sub></b>	<b>G. 10 mc</b>	<b>H. Vitamins</b>	<b>H. 50 mc</b>	<b>I. MgO, Mg Cl<sub>2</sub>, Mg citrate</b>	<b>I. 10 mc</b>	<b>J. Ca Cl<sub>2</sub></b>	<b>J. 10 mc</b>	<b>K. Ca Cl<sub>2</sub></b>	<b>K. 10 mc</b>
<b>A. Vitamins</b>	<b>A. 10 mc</b>																						
<b>B. Amino Acids</b>	<b>B. 10 mc</b>																						
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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.)  
**See attached copies: "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" submitted thru channels to Secretary of the Army 19 Dec 63 by U.S. Army Medical Research and Nutrition Laboratory, Fitzsimons General Hospital, Denver, Colorado, and Memorandum of Approval by Secretary of the Army dated 22 Feb 64. (Incls 1&2)**

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

B. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)		FORMAL COURSE (Circle answer)	
			Yes	No	Yes	No
a. Principles and practices of radiation protection	NA		Yes	No	Yes	No
b. Radioactivity measurement standardization and monitoring techniques and instruments	NA		Yes	No	Yes	No
c. Mathematics and calculations basic to the use and measurement of radioactivity	NA		Yes	No	Yes	No
d. Biological effects of radiation	NA		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
		NA		

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 <sup>2</sup> )	USE (Monitoring, surveying, measuring)
<b>As specified in Application (dtd 6 Dec 63) For License No. 5-46-13 (A66)</b>					

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

**As specified in Application (dtd 6 Dec 63) For License No. 5-46-13 (A66)**

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

**As specified in Application (dtd 6 Dec 63) For License No. 5-46-13 (A66)**

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

**as specified in Application (dtd 6 Dec 63) For License No. 5-46-13 (A66)**

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, serv-

**as specified in Application (dtd 6 Dec 63) For License No. 5-46-13 (A66)**

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will

**as specified in Application (dtd 6 Dec 63) For License No. 5-46-13 (A66)**

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.

Date 12 March 64

Dept of Army, FGH & USA Med Rsch  
& Nutr Lab, Denver, Colo  
Applicant named in item 1  
By: James A. Orbison  
JAMES A. ORBISON  
Colonel, MC  
Title of certifying official  
Chairman, Radioisotope Cmte, FGH

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.

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

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 <b>Department of the Army, Fitzsimons Gen Hospital and USA Med Resch &amp; Nutr Lab</b>	(b) NAME AND ADDRESS OF APPLICANT (if different from 1(a)) <b>Same</b>
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 <b>NA</b>	YES NO CIRCLE ANSWER
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 <b>As specified in Application (dtd 6 Dec 63) For License No. 5-46-13 (A66)</b>	YES NO CIRCLE ANSWER

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): <b>See attached copies: "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" submitted thru channels to Sec'y of the Army 19 Dec 63 by USA Med Resch &amp; Nutr Lab, FGH, Denver, Colo &amp; Memo of Approval by Sec'y of the Army dtd 23 Feb 64 (Incls 1 &amp; 3)</b>	(b) CHEMICAL FORM ADMINISTERED:
(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL <b>As specified in Application (dtd 6 Dec 63) For License No. 5-46-13 (A66)</b>	
(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE (1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) <b>As specified in Application (dtd 6 Dec 63) For License No. 5-46-13 (A66)</b>	YES (NO) CIRCLE ANSWER
(2) ON FILE WITH THE ISOTOPES EXTENSION REFER TO APPLICATION NO <b>5-46-13 (A66)</b>	(YES) NO CIRCLE ANSWER

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): <b>See attached copies: "Request for Approval for Human Use of Radioisotopes in Tracer Amounts in Volunteer Experimental Research Subjects" submitted thru channels to Secretary of the Army 19 Dec 63 by U.S. A. Med Resch &amp; Nutr Lab, FGH, Denver, Colo and Memo of Approval by Secretary of the Army dtd 23 Feb 64 (Incls 1 &amp; 2)</b>	
(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.))	YES NO CIRCLE ANSWER

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. <b>By-product material will be obtained in pre-calibrated form for oral administration or in pre-calibrated and sterilized form for parenteral administration</b>
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7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. <b>NA</b>	YES NO CIRCLE ANSWER
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HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE	YES NO CIRCLE ANSWER
(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	YES NO CIRCLE ANSWER

**APPLICATION FOR BYPRODUCT MATERIAL LICENSE**  
SUPPLEMENT A—HUMAN USE

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

**Item 1 (b) continued: for Human Use of Radioisotopes in Tracer Amounts in  
Volunteer Experimental Research Subjects".**

U. S. ARMY MEDICAL RESEARCH AND NUTRITION LABORATORY  
FITZSIMONS GENERAL HOSPITAL  
DENVER, COLORADO, 80240

IN REPLY REFER TO

MEDEN-CO

19 February 1964

Lt. Col. Irvin C. Plough, MC  
Chief, Medical Research Branch  
U. S. Army Medical Research  
and Development Command  
Office of The Surgeon General  
Department of the Army  
Washington, D. C. 20315

Dear Irv:

The combined general AEC license for FGH & USAMRNL has finally been granted. A copy is inclosed. Everything we requested in the application was approved except for one item: 1(b)"Street Address(es) at Which Byproduct Material Will be Used" in the inclosed page 1 of the original application. We were seeking a streamlined method of getting approval to use isotopes in animals <sup>and humans</sup> in field studies, for example, at Climax, Colo. in the High Altitude Study. You will note in the actual license, Condition 10 limits the use of isotopes to Fitzsimons General Hospital and the U. S. Army Medical Research & Nutrition Laboratory, Denver, Colo. at this address.

I suppose that every specific instance in which we would desire to use isotopes elsewhere would have to be cleared as an amendment to the license? Would it be possible for you to check this out with the Preventive Medicine Division, OTSG to see the best way to handle such a situation in the quickest possible time and with the minimum paperwork and red tape.

As you know, as soon as the approval for human research use of isotopes comes back from the Secretary of the Army, we will submit that to AEC thru channels as an amendment to the general license.

Sincerely,



MARION E. McDOWELL  
Lt. Colonel, MC  
Commanding

Incl:  
a/s