

UNITED STATES ATOMIC ENERGY COMMISSION
APPLICATION FOR BYPRODUCT MATERIAL LICENSE

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided references are clear and specific. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Isotopes Branch, Division of Materials Licensing. 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, person, etc. Include ZIP Code.) Department of the Army Fitzsimons General Hospital and US Army Medical Research & Nutrition Laboratory, Denver, Colorado 80240		(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED (If different from 1 (a). Include ZIP Code.) Same as 1 a.	
2. DEPARTMENT TO USE BYPRODUCT MATERIAL Radioisotope Section, Radiology Service		3. PREVIOUS LICENSE NUMBER(S) (If this is an application for renewal of a license, please indicate and give number) 5-46-13, (A66) (License is presently being renewed.)	
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.) As specified by Fitzsimons General Hospital Radioisotope Committee.		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.) Same as 4.	
6. (a) BYPRODUCT MATERIAL (Elements and mass number of each.) I-131		(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.) Macroaggregated Iodinated Human Serum Albumin 3 millicurie	
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 Form AEC 313a.			

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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)
a. Principles and practices of radiation protection	N/A		Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	N/A		Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity	N/A		Yes No	Yes No
d. Biological effects of radiation	N/A		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
		N/A		

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)
See License #5-46-13 (A66)					

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

See License #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.)

See License #5-46-13 (A66)

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

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
See License #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, servicing, maintenance and repair of the source.
See License #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 be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.
See License #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.

Dept of the Army, FGH & U.S. Army Med.
Rach. & Nutr. Lab., Denver, Colo.

Applicant named in item 1

Date 2 August 1966

By:

EDWIN L. OVERHOLT, Colonel MC
Chairman, Radioisotope Committee

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.

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 Department of the Army Fitzsimons General Hospital and USA Med. Rsch. & Nutr. Lab.	(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a)) 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. As permitted by Fitzsimons General Hospital Radioisotope Committee		(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. As permitted by Fitzsimons General Hospital Radioisotope Committee		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): Macroaggregated Human Serum Albumin will be used for the detection of pulmonary embolism.

(b) CHEMICAL FORM ADMINISTERED: Macroaggregated Iodinated Human Serum Albumin.

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL (See License #5-46-13)(A66) Patient will be premedicated with 10 drops of SSKI given by mouth one hour prior to the IV dose of Macroaggregated Radioiodinated Human Serum Albumin.

(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 License #5-46-13 (A66)

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):

Proposed dosage range 100-350 microcuries.

Radiation exposure to lung - 100-200 mrad.

Radiation exposure to thyroid - (previously blocked with SSKI)

Particle size - 10-25m.

(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:

Macroaggregated Radioiodinated Human Serum Albumin will be obtained in precalibrated sterilized form for parenteral administration from Squibb & Co. or other supplier that meets AEC standards.

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

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

CIRCLE ANSWER

YES NO

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SUPPLEMENT A—HUMAN USE

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

*

3. See License #5-46-13 (1.66)