Form AEC-313
(8-64)
10 CFR 30

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved.
Budget Bureau No. 38-R027

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 U.S.
Army Medical Research and 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

Nuclear Medicine Service

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

Amendment to license No. 05-00046-13

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 and approved by the
Radioisotope Committee
Fitzsimons General Hospital

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 No. 4

6. (a) BYPRODUCT MATERIAL. *(Elements and mass number of each.)*

A) Technetium 99m

(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.)*

Pertechnetate 300 Millicuries

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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(Continued on reverse side)

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	See present license #05-00046-13		Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments			Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity			Yes No	Yes No
d. Biological effects of radiation			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
	See present license #05-00046-13			

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)
See present license #05-00046-13					

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

See present license #05-00046-13

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

See present license #05-00046-13

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 present license #05-00046-13

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 present license #05-00046-13

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 present license #05-00046-13

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 & US Army Med. Rsch & Nutr Lab, Denver, Colo. 80240
Applicant named in item 1

Date 17 Oct 69

By: Paul E. Siebert
Paul E. Siebert, Col. MC
Chairman, Radioisotope Committee
Title of certifying official

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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 : 1964 O—745-382

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(11-63)
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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

Department of the Army
Fitzsimons General Hospital and U.S. Army
Medical Research and Nutrition Laboratory

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

Denver, Coloraod 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 specified by the Radioisotope Committee Fitzsimons Gen. Hosp. 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): For liver and spleen scanning. For the diagnosis of space occupying lesions (tumor, abscess, etc.), obstructive diseases, intrahepatic disease, and diseases of the reticuloendothelial system.

(b) CHEMICAL FORM ADMINISTERED:

Tc99m Sulfur Colloid

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

See present license #05-00046-13 plus attached sheet.

(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. 05-00046-13 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):

1 - 3 Millicuries

(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:

See attached sheet.

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

Request cont'd:

The Tesuloid (Sulfur Colloid Kit) list #08856, manufactured by the E. R. Squibb and Sons,Co. will be used for the use of liver and spleen scanning. This kit was approved for use by the AEC on 13 June 1969 and has been recorded in their records.

No more than 5.0 ml of the eluate of Tc 99m will be used for the preparation of the sulfur colloid in the Tesuloid kit per vial. Procedure for the preparation of the sulfur colloid kit from the E. R. Squibb and Sons, Co. will be as follows: (All vials and reagents will be contained in lead except for boiling stage).

1. Tc 99m (no more than 5 ml) will be injected aseptically into a vial. If there is evidence of contamination from either the generator, kit or technique the materials will not be used.
2. To the shielded Technetium vial will be added aseptically a mixture of the contents of Unimatic(R) disposible syringe A containing 0.25 normal hydrochloric acid. The contents of the vial will be gently shaken. Tongs will be used to handle the mixture.
3. The contents of the vial will then be emersed in a boling water bath (95°C + or - 5°C) which is deep enough to cover the contents of the vial and this will be heated for a period of 10 + or - 2 min. The water bath will be shielded in lead. After boiling, the vial will be removed with tongs and allowed to cool for 5 min. in a lead shielded area.
4. The sterile buffer solution from the Unimatic (R)disposible syringe B will be injected aseptically into above vial, and again gently shaken. No more than 3.0 mCi of Tc 99m sulfur colloid will be used per patient.

Request cont'd:

The activity can easily be obtained by decaying the Tc 99m initially eluded, and also checked by the Nuclear Chicago Meteor Dose Calibrator. The calculator is calibrated regularly with a standard source.

Following the intravenous injection of Tc 99m sulfur colloid, the first patient so injected with the prepared colloid will be monitored as to significant lung labelling with colloid or any free Pertechnetate. Using a very narrow window the Nuclear Chicago thyroid uptake probe may be utilized to determine the percentage of labelling of the lung and thyroid respectively. If there is evidence of 10% uptake of Tc 99m in the thyroid from the administered dose the batch will be discarded. Also if there is significant labelling of the lung indicating particle size greater than 1 micron the batch will be discarded. Prototype testing has been done in other laboratories in this area and have been found not to be a problem.

The sterility and pyrogenicity of the Mo 99 Generator and Tesuloid kit have been previously evaluated by E. R. Squibb and Sons and have been found satisfactory for human use.

2 mCi of prepared Technetium sulfur colloid will deliver to the liver 0 66-0.72 Rads. The whole body dose in Rads with the Technetium labelled sulfur colloid is 0.03 Rads. In contra-distinction gold 198 colloid delivers a dose of 5.7 Rads to the liver and 0.35 Rads to the whole body following 150 uCi of colloidal gold 198. From the proven safety of the Technetium sulfur colloid by those using Technetium labelled sulfur colloid it would seem appropriate that our request be approved.

Eugene T. Morita, Maj. MC