Form AEC-313 (9-55)

ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form Approved. Budget Bureau No. 38-R027.3.

DUPLICATED FOR DIV. OF INSP.

INSTRUCTIONS: Complete Items 1 through 19 if this is a new application. If renewal is requested, complete only Items 1 through 11 provided that with respect to the other items there has been no change in the information previously submitted. Mail two copies to: U. S. Atomic Energy Commission, P. O. Box E, Oak Ridge, Tennessee, Attention: Isotopes Extension, Division of Civilian Application. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. General requirements for issuance of an AEC Byproduct Material License are contained in Title 10, Code of Federal Regulations, Part 30.

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

Veterans Administration Center
Wilshire and Sawtelle Blvds.
Los Angeles 25, California

(b) ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED (*If different from shipping address*)

Same

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Radioisotope Service

3. INDIVIDUAL USER (*Name and title of individual(s) who will use or directly supervise use of byproduct material*)

William H. Blahd, M.D., Chief, Radioisotope Service, and Nome Baker, Ph.D., Principal Scientist

4. RADIOLOGICAL SAFETY OFFICER (*Name of person qualified in radiological safety, if other than individual user*)

5. PREVIOUS LICENSE OR AUTHORIZATION NUMBER (*If this is an application for renewal of a license for byproduct material obtained under a prior license or authorization for radioisotope procurement*)

Other Carbon-14 Licenses are 4-181-2 and 4-181-5

BYPRODUCT MATERIAL OR IRRADIATION SERVICE DESIRED

6. BYPRODUCT MATERIAL (*Element and mass number*)	7. CHEMICAL AND/OR PHYSICAL FORM (*Or catalog number*)	8. MAXIMUM AMOUNT OF RADIOACTIVITY IN MILLICURIES THAT YOU WILL POSSESS AT ANY ONE TIME
Carbon-14	Glucose-C14 Glutamine-1-C14 Lactic Acid-1-C14 Lactic Acid-2-C14	1 mc. each

9. IF IRRADIATION SERVICE IS DESIRED, STATE PERTINENT DETAILS SUCH AS: CHEMICAL COMPOSITION AND WEIGHT IN GRAMS OF TARGET MATERIAL, RADIOACTIVITY, IRRADIATION TIME IN DAYS, AND NEUTRON FLUX

STATEMENT OF USE

10. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. (*If material is for "human use" complete Supplement A in lieu of this item. If material is to be used in or manufactured as a "sealed source" complete Supplement B in addition to this item.*)

Study of rates of turnover and oxidation in muscular dystrophic subjects and in biological laboratory studies for use in lower animals.

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

See Licenses No. 4-181-2 and 4-181-4

CERTIFICATE

11. 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 do solemnly swear (or affirm) that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

State of .....

County of .....

Subscribed and sworn to before me this ..... day of .....

Notary Public

Veterans Administration Center
Applicant named in Item 1

By Wm. H. Blahd

Wm. H. Blahd, M.D., Chief, Radioisotope Serv.
Title of Certifying Official

12-5-56
Date

WARNING

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

A. GRAHAM KOSLEY, JR.
Radioisotope Division
Chief, Radioisotope Service
Atomic Medicine Division
Administration

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ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

INSTRUCTIONS: Complete Items 12 through 19 if this is a new application. This information may be omitted from subsequent applications provided there is no change in the information previously submitted, and reference is made in Item 5 to the application on which this information appears.

TRAINING AND EXPERIENCE WITH RADIOACTIVITY OF INDIVIDUAL USER NAMED IN ITEM 3

12. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
1. Principles and practices of radiological health safety.	See previous applications from this Center and from Veterans Administration Hospital, Cleveland		Yes No	Yes No
2. Radioactivity measurement standardization and monitoring techniques and instruments			Yes No	Yes No
3. Mathematics and calculations basic to the use and measurement of radioactivity.			Yes No	Yes No
4. Biological effects of radiation. . .	See License No. 4-181-4		Yes No	Yes No
5. Actual use of radioisotopes in the types and quantities for which application is being made, or equivalent experience			Yes No	Yes No

13. ISOTOPE HANDLING EXPERIENCE

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
See License	No. 4-181-4			

14. If Radiological Safety Officer named in Item 4 is different from individual user named in Item 3, use supplementary sheet to provide equivalent information on "Training and Experience With Radioactivity of Radiological Safety Officer." Supplementary sheet is attached (*Circle answer*) Yes No

PHYSICAL FACILITIES, EQUIPMENT, AND RADIATION INSTRUMENTATION

15. RADIATION DETECTION INSTRUMENTS (*Use separate sheet 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 License No. 4-181-2					

16. FILM BADGES, DOSIMETERS, AND OTHER PERSONNEL MONITORING DEVICES INCLUDING BIO-ASSAY PROCEDURES

See License No. 4-181-2

17. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE (*For film badges specify method of calibration and processing, or name supplier*)

See License No. 4-181-2

18. (*a*) DESCRIBE BRIEFLY REMOTE HANDLING EQUIPMENT, STORAGE CONTAINERS, SHIELDING, AND LABORATORY FACILITIES (*Working areas, fume hoods, etc.*)

See License No. 4-181-2

(*b*) SKETCHES OF SUCH FACILITIES ARE ATTACHED (*Circle answer*) Yes No

19. DESCRIBE BRIEFLY RADIATION SURVEYING PROCEDURES AND METHODS OF DISPOSING OF RADIOACTIVE WASTES

See License No. 4-181-2

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4-181-5

Form AEC 313a (9-55)

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

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DUPLICATED FOR DIV. OF INSP.

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

QUALIFICATIONS OF PHYSICIAN WHO WILL SUPERVISE USE OF BYPRODUCT MATERIAL

1. THE INDIVIDUAL USER(S) ITEM 3, PAGE ONE, OF THIS APPLICATION IS (ARE) LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE IN THE STATE OR TERRITORY WHERE THE BYPRODUCT MATERIAL WILL BE USED.	CIRCLE ANSWER	YES	NO

2. CLINICAL TRAINING AND EXPERIENCE WITH BYPRODUCT MATERIAL

NOTE: Customarily item 2 is completed and signed by the preceptor. *(See instructions.)*

(A) ISOTOPE	(B) TOTAL NUMBER OF HOURS OF PARTICIPATION IN TRAINING PROGRAM	(C) CONDITION(S) DIAGNOSED OR TREATED *(e. g., diagnosis of thyroid function, treatment of hyperthyroidism)*	(D) NUMBER OF CASES	(E) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN D *(circle applicable numbers of items in accordance with key set forth below)*
See License No. 4-181-4				1 2 3 4 5 6 7 8
				1 2 3 4 5 6 7 8
				1 2 3 4 5 6 7 8
				1 2 3 4 5 6 7 8
				1 2 3 4 5 6 7 8
				1 2 3 4 5 6 7 8

Key to above numbers

Active participation and observation

1. Evaluation of the suitability of the patient for radioisotope diagnosis and/or treatment by taking patient histories and performing medical examinations and/or study of case histories.
2. Collaboration in diagnosis and/or treatment and dosages prescribed.
3. Measurement of doses and their administration.
4. Related measurements and plotting of data.
5. Active period of training and experience of *sufficient duration* to permit the following of specific patients through treatment and post-treatment periods, including reevaluation as to effectiveness and complications.
6. Study of case histories (without seeing patients).
7. Study of case histories (observed patients).
8. Observation and discussion of diagnostic and/or therapeutic techniques, as well as management of patients during follow-up periods.

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

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

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

4. (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
5. PATIENTS CONTAINING MORE THAN 30 MILLICURIES OF RADIOACTIVITY WILL BE HOSPITALIZED UNTIL BODY CONTENT OF RADIOACTIVITY IS LESS THAN 30 MILLICURIES *(see instructions)*.	CIRCLE ANSWER	YES	NO

Form AEC-313a

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

PROPOSED DIAGNOSIS OR TREATMENT

6. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED:

Study rates of turnover and oxidation in muscular dystrophic subjects.

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

See Licenses 4-181-2 and 4-181-4

PROPOSED DOSAGE SCHEDULE

7. Complete this item for new or unusual uses only

(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 additional sheet if necessary)

A maximum of one dose containing 0.1 millicurie will be administered to each subject.

8. CHEMICAL FORM ADMINISTERED: Glucose-C^{14}, Glutamine-1-C^{14}, Lactic Acid-1-C^{14}, Lactic Acid-2-C^{14}

9. 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 License No. 4-181-2

EXPERIMENTAL PROGRAMS AND NEW OR UNUSUAL USES

10. INVESTIGATIVE PROPOSAL IS ATTACHED OUTLINING STUDY CONDITIONS TO BE EVALUATED, RATIONALE FOR PROPOSED USE AND DOSAGE INCLUDING DATA FROM ANIMAL STUDIES AND/OR LITERATURE REFERENCES IF AVAILABLE, NUMBER AND TYPE OF PATIENTS (E. G., AGE GROUP, MORIBUND, ETC.).	CIRCLE ANSWER	YES	(NO)
11. DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE (a) ATTACHED (LITERATURE REFERENCES WILL SUFFICE)	CIRCLE ANSWER	YES	(NO)
(b) ON FILE WITH THE ISOTOPES EXTENSION REFER TO APPLICATION NO:	CIRCLE ANSWER	YES	(NO)
12. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE	CIRCLE ANSWER	(YES)	NO

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