Form AEC-313 (5-58)

ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

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

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.

Amend 6
20-551-7

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

Richard Gorlin, M.D.
721 Huntington Avenue
Boston 15, Massachusetts

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

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Cardiovascular Division
Department of Medicine

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

Renewal 20-551-7 (D62)

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.)*

Richard Gorlin, M.D.
Asst. Professor of Medicine
Harvard Medical School
Sr. Associate in Medicine
Peter Bent Brigham 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.)*

Robert G. Moffat, M.D.

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

Krypton 85

(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.)*

Krypton 85 gas, 1 curie (13 ml.) in 150 ml. metal cylinder (sealed source)
Supplied by Union Carbide Nuclear Company
Oak Ridge National Laboratory
PO Box X, Oak Ridge, Tennessee

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.)*

DUPLICATED
FOR DIV. OF COMPLIANCE

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(Continued on reverse side)

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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	Peter Bent Brigham Hospital	5½ yrs	(Yes) No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Mass. Gen. Hosp Isotope Committee Lectures on Radioisotopes & Radiological Health	May 3 to June 9, 1960	(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
I-131	30μ maximum dose & up to 100 μ per patient	US Naval Hosp., Portsmouth Virginia	6 mos	diagnostic studies of cardiac function including blood volumes
		Peter Bent Brigham Hospital	5½ yrs	

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)
portable survey meter	#881-1	γ	.02-25	β 860	monitor, survey, measure.
scintillation probe detector	#810-1	γ		β 30	
decade scaler	#2105-1	γ			measure
film badges	20				measure

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

I-131 standard obtained from Nuclear Chicago

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

film badges developed weekly through N.E. Deaconess Hospital and Peter Bent Brigham Hospital, Radiation Committee (used by all personnel in area)

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 See form AEC 313a, #4C

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.

As outlined in Bureau of Standards Handbook #42

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.

Subscribed and sworn to (affirmed) before me this 23 day of March 1962

In the City of Boston, County of Suffolk, Commonwealth of Massachusetts.

Date March 23, 1962

William E. Hanamirian
NOTARY PUBLIC
MY COMMISSION EXPIRES
AUGUST 2, 1963

Applicant named in item 1

By: Robert Moffat M.D. Chairman

PBBH 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.

U.S. GOVERNMENT PRINTING OFFICE: 1960 O - 568572

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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

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
Richard Gorlin, M.D.
721 Huntington Avenue
Boston 15, Mass.

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

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)
Diagnostic: determination and other regional blood flow's, residual volumes, cardiac outputs
Conditions: heart failure, valvular heart disease, coronary artery disease

(b) CHEMICAL FORM ADMINISTERED
1. gas dissolved in saline solution
2. single-breath inhalation of the gas dissolved in predetermined mixture of air

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:
Gas will be stored in lead shielded enclosure within exhaust hood*. All transfer of gas will be performed within hood, gloves will be worn and discarded, syringes capped and transported in lead-lined metal pan. After use, syringes will be returned to hood for escape of gas and reactivity via exhaust.

(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 _____
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):
50μ per injection will be administered 1-6 times to a total of 300μ per study. Because of its extremely short biological half life (2-4 min), the total body exposure can be estimated at a maximum of 0.7 millirem and with probable tracheal exposure equal to 100 millirem maximum

(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:

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

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. Please cross reference to specific items.

4 (c). After injection into the patient of the gas-saline mixture, expired air will be collected in a large Douglas Bag for 5 minutes. The bag will then be emptied into the exhaust system. The area of handling and of administration will be monitored by portable survey meter and background change of study room will be additionally followed on a gamma scintillation counter used in investigations

* * An all metal system for storing and handling Kr-85 has been patterned after the system designed by Dr. Charles Robinson and currently in use at the New England Medical Center, Boston, Mass. Our system will consist of 2 vertical storage cylinders each of 8 cc. volume connected by packless, metal bellows valves into a common tube with a 0 to 30 inches Hg. Bourbon-type vacuum gauge. This tube will in turn connect by another metal valve to a measuring section of about 3 cc. volume which will include a small finger trap. The measuring section will be connected by metal valves to a vacuum pump and to a delivery, or filling, section. The system will be set up in a shielded hood which is vented above the roof (by a duct with no other connection).

To fill the system, the Kr-85 shipping container will be attached to the filling section, the storage containers and connections will be evacuated, then the valve to the vacuum pump will be closed and the valve of the shipping container opened. Liquid nitrogen will be placed around one of the storage containers until the increase of negative pressure registered on the gauge indicates half of the krypton has been removed from the gas phase. Then the valve to the first storage container will be closed and liquid nitrogen will be placed around the other storage container until a negative pressure of 30 inches of mercury is attained, and then all the valves will be closed. Approximately half of the gas will be trapped into each of the 2 storage containers. Since 1 curie of Kr-85 will not be more than 15 cc. S.T.P. the pressure in each storage container will never be more than atmospheric. During storage these containers will be shielded with lead.

To remove gas from the system the valves will be opened between one of the storage containers and the measuring section. Gas will be transferred to the measuring section by cooling its finger until there is a drop in pressure of about ½ atmosphere. The valves between the storage container and the measuring section will be closed and the finger brought to room temperature to give about 3 cc of gas at near atmospheric pressure. Part of this will then be withdrawn through the valve to the deliver y section. When the withdrawal is complete the valve to the delivery section will be closed, the valves between the storage compartment and the measuring section will be opened, liquid nitrogen will be placed around the storage cylinder and the krypton will be drawn back into its original container.

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