For Div. of Compliance

30-2671 9/30/63

Form AEC-313 (5-58)

ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved. Budget Bureau No. 38-R027.4.

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.

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

Lakewood Hospital
14519 Detroit Avenue
Lakewood 7, Ohio

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

Same

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Nuclear Medicine

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

34-1197-1 RENEWAL

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.)*

William J. Fayen, M. D.
Director, Radioisotope Laboratory

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.)*

Thomas W. Knickerbocker, M. D.
Director of Radiology

6. (a) BYPRODUCT MATERIAL. *(Elements and mass number of each.)*	(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.)*
A. Iodine 131	A. Iodide, solution or capsules - 100 mc.
B. Iodine 131	B. Iodinated human serum albumin - 2 mc.
C. Iodine 131	C. Labeled fat and/or fatty acids - 1 mc.
D. Phosphorus 32	D. Soluble phosphate - 50 mc.
E. Cobalt 60	E. Labeled vitamin B 12 - 5 μc.
F. Mercury 203	F. Neohydrin - 5 mc.
G. Chromium 51	G. Sodium Chromate - 5 mc.
H. Gold 198	H. Colloidal - 20 mc.

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.)*

A10

54502

Form AEC-313 (5-58) Page Two

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			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

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)
Nuclear-Chicago Pho-Dot Scanner has replaced Picker Magnascanner Other equipment described in original application	1	Gamma	--	--	Scanning

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

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

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

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.

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.

A10

RECEIVED OCT 3 1963 U.S. Atomic Energy Commission Division of Licensing & Regulation

Date September 30, 1963

Lakewood Hospital
Applicant named in item 1

By: William J. Fayen
William J. Fayen, M. D.
Chairman, Isotope 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 : 1961 OF—615965

Item 15 - WASTE DISPOSAL

Radioactive wastes are flushed into the hospital sewer directly from the waste commode in the laboratory. Amounts disposed are up to 10 microcurie level.

Form AEC-313 a (10-61) Page 1

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

William J. Fayen, M. D.

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

Lakewood Hospital, 14519 Detroit Avenue
Lakewood 7, Ohio

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):

See Page 2

(b) CHEMICAL FORM ADMINISTERED:

See Page 2

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

(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. (a) PROPOSED DOSAGE SCHEDULE.—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):

A. I-131 - Thyroid Diagnosis - 5-50 μc.
Hyperthyroidism - 3-40 mc.
Cardiac States - 10-40 mc.
B. I-131 - Blood Volumes - 2-5 μc.
C. I-131 - Fat Studies - 25-50 μc.
D. P-32 - Leukemia & Polycythemia - 2-10 mc.
E. Co-60 - PA Diagnosis - 0.5 μc.
F. Hg-203 - Brain Scan - up to 700 μc.
Kidney Scan - 50-100 μc.
G. Cr-51 - Red Cell Survival - 50-100 μc.
H. Au-198 - Liver Scan - 100-200 μc.

(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

Form AEC-313 a
(10-61)
Page 2

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved.
Budget Bureau No. 38-R0801

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

4 (a) Describe purpose for which byproduct material will be used including specific conditions or diseases to be diagnosed or treated:

A. I-131 - Diagnosis of thyroid function
   Treatment of hyperthyroidism and cardiac dysfunction
B. I-131 - Determination of blood volume
C. I-131 - Fat absorption studies
D. P-32 - Treatment of polycythemia vera and leukemia
E. Co-60 - Diagnosis of pernicious anemia
F. Hg-203 - Brain and kidney scans for tumor localization
G. Cr-51 - Red cell survival studies
H. Au-198 - Liver scans for tumor localization

4 (b) Chemical form administered:

A. I-131 - Iodide - solution or capsules
B. I-131 - Iodinated Human Serum Albumin
C. I-131 - Labeled fats and/or fatty acids
D. P-32 - Soluble Phosphate
E. Co-60 - Labeled Vitamin B-12
F. Hg-203 - Neohydrin
G. Cr-51 - Sodium Chromate
H. Au-198 - Colloidal Suspension

U.S. GOVERNMENT PRINTING OFFICE : 1961 O-615963