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.

Amend. 15

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

Lakewood Hospital
14519 Detroit Ave.,
Lakewood, Ohio 44107

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

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.)

34-1197-01 - Renewal with Additions

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, Nuclear Medicine

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.)

Wilfred M. Gill, M.D.
Associate Radiologist

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.)	
RENEWAL		
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35
B. Molybdenum 99	B. Molybdenum 99/Technetium 99m Generators, including E.R. Squibb, Abbott, NEN, Mallinckrodt, Cambridge	B. 1000 millicuries
C. Phosphorus 32	C. Soluble Phosphate	C. 500 millicuries
D. Selenium 75	D. Methionine	D. 3 millicuries
E. I 131	E. Iodide	E. 100 millicuries
F. Cesium 137	F. Any	F. 2 millicuries
G. Technetium 99m	G. Sulfur Colloid	G. 100 millicuries

** In addition, permission is requested for the authorized use of the by-product materials appearing on Page 2 B. See H, I, J and K

H. I 125 or I 131	H. Triiodothyronine and/or Thyroxine	H. 1 millicurie

(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	See previous applications		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 previous applications				

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 previous applications					

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

See previous applications

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

See previous applications

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 previous applications

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 previous applications

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.

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Date September 11, 1972

Lakewood Hospital
Applicant named in item 1

By: Peter M. Dominy
Administrator
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 : 1964 O—748-382

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

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. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, CFR 35
B. Molybdenum 99	Production of Technetium 99m Pertechnetate
C. Phosphorus	Treatment of leukemia, polycythemia vera, bone metastases
D. Selenium 75	Pancreas scans
E. I 131	Treatment of hyperthyroidism and cardiac dysfunction
F. Cesium 137	For use as a standard for calibration
G. Technetium 99m	Liver and spleen scans
H. I 125 and I 131 (addition)	In vitro thyroid studies

I, J and K - details of preparation and usage appear on a separate page - permission for use is requested.

(b) Chemical form administered.

A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of CFR 35	As set forth in Groups I and II of Schedule A, Section 35.100 of Title 10, CFR 35
B. Molybdenum 99	Sodium pertechnetate
C. Phosphorus	Sodium phosphate
D. Selenium 75	Selenomethionine
E. I 131	Sodium iodide
F. Cesium 137	Standard for calibration
G. Technetium 99m	Technetium 99m sulfur colloid
H. I 125 and I 131 (addition)	Triiodothyronine and/or thyroxine

I, J and K - details of preparation and usage appear on a separate page - permission for use is requested.

(c) Proposed dosage schedule.

A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of CFR 35	As set forth in Groups I and II of Schedule A, Section 35.100 of Title 10, CFR 35.
B. Molybdenum 99	As set forth in Groups I and II of Schedule A, Section 35.100 of Title 10, CFR 35
C. Phosphorus	Polycythemia and leukemia - 2-10 millicuries
D. Selenium 75	Pancreatic scanning - 250 microcuries
E. I 131	Hyperthyroidism - 3-40 millicuries
F. Cesium 137	Cardiac states - 10-50 millicuries
G. Technetium 99m	Instrument standardization - 1 millicurie
H. I 125 and I 131 (addition)	Liver and spleen scanning - 3 millicuries
	In vitro thyroid studies

I, J and K - details of preparation and usage appear on a separate page - permission for use is requested.

* U.S. GOVERNMENT PRINTING OFFICE : 1968 O—322-213

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(11-63)
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UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved.
Budget Bureau No. 38-R0080

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). Include ZIP Code.)

Lakewood Hospital
14519 Detroit Ave., Lakewood, Ohio

	CIRCLE ANSWER	
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.	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. See previous applications	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 detail on Page 2 A

(b) CHEMICAL FORM ADMINISTERED.

See detail on Page 2 A

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

See previous applications

	CIRCLE ANSWER	
(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE (1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE)	YES	NO
(2) ON FILE WITH THE ISOTOPES BRANCH REFER TO APPLICATION NO _____	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).

See detail on Page 2 A

	CIRCLE ANSWER	
(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.))	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.

	CIRCLE ANSWER	
7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE.	YES	NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

	CIRCLE ANSWER	
8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE.	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.	YES	NO

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

** In addition, permission is requested for the authorized use of the following byproduct materials.

I.	Technetium 99m	I. Labeled albumin microspheres (human) prepared by the licensee using the 3M kit.	I. 100 Millicuries
J.	Technetium 99m	J. Iron-ascorbate-diethylene-triamine penta-acetic acid complex prepared by the licensee using the Squibb kit.	J. 50 Millicuries
K.	Technetium 99m	K. Sulfur colloid prepared by the licensee using the Mallinckrodt kit. (Permission for use of the Squibb kit has been previously approved.)	K. 100 Millicuries

The above (I, J, K) are to be prepared and administered according to the accompanying specifications and regulations.

See following statements (3) Page 2 B Con't.

Lakewood Hospital
Lakewood, Ohio
9/11/72

* U.S. GOVERNMENT PRINTING OFFICE : 1968 O—322-213

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UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved.
Budget Bureau No. 38-R0080

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

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):

(b) CHEMICAL FORM ADMINISTERED:

(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 BRANCH 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):

(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

I. Technetium 99m labeled albumin microspheres

It is requested that our current AEC license No. 34-1197-01 be amended to include the use of technetium 99m labeled albumin microspheres (human) for lung imaging. The dose will not exceed 4 millicuries.

To prepare the technetium 99m labeled albumin microspheres for human use, we will combine the assayed, sterile, pyrogen free Tc 99m eluate from an AEC approved Mo 99 Tc 99m generator with the components of the 3M Nuclear Products Co. Albumin Microsphere Tc 99m Labeling kit. Manufacturer's directions for preparation will be followed.

Tc 99m eluate will not be used if Mo 99 contamination exceeds 1.0 microcuries per 1.0 millicuries of Tc99m.

All vials of radioactive material will be kept in lead containers during preparation and storage of each batch. Lead shields will be used on syringes containing radioactive material. Laboratory personnel will wear appropriate film badges and monitor the area with the required survey instruments when necessary.

The completed preparation will be assayed using a Radex Mark V Isotope Dose Calibrator. Since 10 ml of the Tc99m eluate will be used in preparing the labeled microspheres, the resulting completed product will have the same total activity as the original 10 ml of Tc 99m, corrected for loss due to decay.

Lakewood Hospital
Lakewood, Ohio
9/11/72

J. Technetium 99m Diethylenetriamine-penta acetic acid (Tc99m-DTPA)

It is requested that our current AEC license No. 34-1197-01 be amended to include the use of Technetium 99m Diethylenetriamine penta acetic acid (Tc99m-DTPA) for kidney scanning. Maximum dose will not exceed 5 millicuries.

To prepare the Tc99m-DTPA for human use, will will combine the assayed, sterile, pyrogen free Tc99m eluate from an AEC approved Mo99Tc99m generator with the components of the Squibb Renotec kit, (List No. 08897).

Tc99m eluate will not be used if Mo99 contamination exceeds 1.0 microcuries per 1.0 millicuries of Tc99m .

Manufacturer's directions for preparation will be followed.

All vials of radioactive materail will be kept in lead containers during preparation and storage of each batch. Lead shields will be used on syringes containing radioactive material. Laboratory personnel will wear appropriate film badges and monital the area with the required survey instruments when necessary.

To determine assay of the completed preparation: since 5 ml of the Tc99m eluate (activity to be determined using a Radex Mark V Istotpe Dose Calibrator) will be mixed with 6 ml of non-active Renotec material, the resulting 11.0 ml of Tc99m-DTPA will have the same total activity as the original 5.0 ml of Tc99m, corrected for loss due to decay.

Lakewood Hospital
Lakewood, Ohio
9/11/72

K. Technetium 99m labeled sulfur colloid

It is requested that our current AEC license No. 34-1197-01 be amended to include the use of the Mallinckrodt-Nuclear TechneColl kit, Catalog No. 090, for the preparation of Technetium 99m Sulfur Colloid. The dose will not exceed 3 millicuries.

Technetium 99m will be obtained from an AEC approved Mo 99 Tc 99m generator. Elution and assay procedures will be carried out as previously set forth in our letter of August 14, 1970, requesting amendment to our AEC license No. 34-1197-01 for the use of a Mo99 Tc99m generator.

The procedure for preparation of the Tc99m Sulfur Colloid as recommended by the manufacturer will be followed.

The final product will be assayed using the procedure recommended by the generator manufacturer. Up to a 5 ml portion of the Mo99Tc99m generator eluate (calibrated by a Radx Mark V Isotope Dose Calibrator) will be added to a vial of the same type and dimensions as the Tc99m sulfur colloid reaction vial of the same type and dimensions as the Tc99m sulfur colloid reaction vial and diluted to a volume equal to the final volume of the kit product. A calibration factor for the volume obtained above will be determined and used in subsequent calibration of the Tc99m sulfur colloid products.

The Tc99m eluate will be obtained from the generators listed in AEC 313 Item 6 B of license No. 34-1197-01.

Tc99m sulfur colloid will be prepared by following the recommended procedure of the manufacturer. With the first patient dose administered from each batch the count rate over the patient's lung area will be compared to the count rate over the liver. If a lung uptake of greater than 10% is encountered the remainder of the batch will not be used. The amount of free Tc99m will be determined by comparing the count rate of the heart to the liver. If a value of 10% or greater is obtained the rest of the batch will not be used.

Except during the heating process the reaction will will be shielded by a 1/4 inch lead vial safe. Heating of the reaction vial will take place behind a lead brick wall or a minimum 1/8 inch lead safe.

Lakewood Hospital
Lakewood, Ohio
9/11/72