

UNITED STATES ATOMIC ENERGY COMMISSION
APPLICATION FOR BYPRODUCT MATERIAL LICENSE

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: Materials Branch, Directorate of 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, and the license fee provisions of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 16 and the appropriate fee enclosed. (See Note in Instruction Sheet).

1. (a) NAME AND STREET ADDRESS OF APPLICANT. (Institution, firm, hospital person, etc. include ZIP Code and telephone number.) (b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. (If different from 1(a). Include ZIP Code.)

Medical X-Ray Center, P.C.
1417 South Minnesota Avenue
Sioux Falls, South Dakota 57105

SAME

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Same as above.

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

40-01493-02

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.)

Donald H. Breit, M.D. R. P. DeClark, M.D.
Donald J. Peik, M.D. D. R. Wierda, M.D.
Bryson R. McHardy, M.D. R. L. Read, M.D.
M. F. Petereit, M.D. L. A. Henrickson, M.D.
L. J. Larson, M.D. James Quale, M.D.

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.)

Donald J. Peik, M.D., Radiologist

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

Group II, III

A. Iodine 131
B. Phosphorus 32

- (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 source and maximum activity per source.)

A. Iodide 100 millicuries
B. Soluble phosphate 12 millicuries

RECEIVED BY LFMS
Date 12/13/77
To: Jm
By: Weiss
From:
To:
Action Comd 12/13/77

Applicant
Check No. 19099
Amount 110-ret'd
Date of Check 12-7-77
Date Check Rec'd 12-13-77
Received By: Weiss

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.)

Human use - A. Treatment of hyperthyroidism, and cardiac dysfunction. Diagnosis of thyroid function.

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TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 1 (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 supplemental sheet, attached. | | 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 supplemental sheet, attached. | | |

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) |
|--|------------------|--------------------|------------------------------|---|---|
| Victoreen Survey Meter | 1 | beta and gamma | mr/hr | | surveying |
| Pickler Cliniscaler Model 628150 | 1 | beta and gamma | cpm | | measuring |

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

All equipment checked and calibrated by certified radiation physicist at least yearly. Batteries (in units using batteries) checked weekly or more often if any reason to.

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

Film badge service: R. S. Landauer, Jr., & Co. reported monthly (WHOLE BODY)
Bioassay, commercial Mallinckrodt/Nuclear2703 Wagner Pl., Maryland Hts., MO 63043

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 attached sheets

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 attached sheets

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 attached sheets

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 THE 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.

License Fee Category \$ 110.00 - Human Use 7-C

Fee Enclosed \$ 110.00

Medical X-Ray Center, P.C.

Applicant named in item 1

By:

DONALD H. BREIT, M.D., RADIOLOGIST

Director

Title of certifying official

Date December 7, 1977

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.

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 Medical X-Ray Center 1417 S. Minnesota Avenue Sioux Falls, South Dakota 57105 | | 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 <input checked="" type="radio"/> NO <input type="radio"/> |
| 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 attached supplemental sheets | | CIRCLE ANSWER | YES <input type="radio"/> NO <input type="radio"/> |
| 4. A DESCRIPTION OF THE USING PHYSICIAN'S TRAINING AND EXPERIENCE IN BASIC RADIOISOTOPE HANDLING TECHNIQUES AND/OR RADIOPHARMACEUTICAL PREPARATION IS APPENDED. See attached supplemental sheets | | CIRCLE ANSWER | YES <input type="radio"/> NO <input type="radio"/> |
| 5. (a) DESCRIBE PURPOSE FOR WHICH MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary): Treatment of hyperthyroidism, and cardiac dysfunction. Diagnosis of thyroid function. (b) CHEMICAL FORM ADMINISTERED: Iodide Soluble phosphate (c) DOSAGE SCHEDULE FOR EACH CONDITION TO BE DIAGNOSED OR TREATED: | | | |
| 6. INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL OR NON-ROUTINE USE IS APPENDED (See Appendix F of AEC Licensing Guide for items to be submitted) | | CIRCLE ANSWER | YES <input type="radio"/> NO <input checked="" type="radio"/> |
| 7. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES: Obtained in precalibrated form | | | |
| 8. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. | | CIRCLE ANSWER | YES <input type="radio"/> NO <input checked="" type="radio"/> |
| HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY | | | |
| 9. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE. | | CIRCLE ANSWER | YES <input type="radio"/> NO <input type="radio"/> |
| (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 <input type="radio"/> NO <input type="radio"/> |

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APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL
SUPPLEMENT A—HUMAN USE

PAGE 2

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

DONALD H. BREIT, M.D.
DONALD J. PEIK, M.D.
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M. FRANK PETEREIT, M.D.
LELAND J. LARSON, M.D.
ROBERT P. DE CLARK, M.D.
DARYL R. WIERDA, M.D.
RALPH L. READ, M.D.
LYNN A. HENRICKSON, M.D.
JAMES QUALE, M.D.

RADIOLOGISTS

MEDICAL X-RAY CENTER, P.C.

1417 SOUTH MINNESOTA AVENUE
SIOUX FALLS, SOUTH DAKOTA 57105
605-336-0515

X-RAY DIAGNOSIS
X-RAY THERAPY
RADIUM THERAPY
RADIOACTIVE
ISOTOPES
COBALT THERAPY
SPECIAL PROCEDURES
F. R. CZESWIK
BUSINESS MANAGER

FORM AEC-313

Item 8 - ABCD

| | |
|--------------------------|---------------------------|
| Donald H. Breit, M.D. | University of Nebraska |
| Donald J. Peik, M.D. | Milwaukee County Hospital |
| Bryson R. McHardy, M.D. | Michael Reese Hospital |
| M. Frank Peterreit, M.D. | Denver General Hospital |
| Leland J. Larson, M.D. | Mayo Clinic |
| Robert P. DeClark, M.D. | University of Iowa |
| Daryl R. Wierda, M.D. | University of Colorado |
| Ralph Read, M.D. | University of Minnesota |
| Lynn Henrickson, M.D. | University of Minnesota |
| James Quale, M.D. | University of Colorado |

All certified by American Board of Radiology

Item 9

Donald J. Peik, M.D., Radiologist, Radiation Safety Officer

Training: Residency, Radiology, Milwaukee County Hospital,
Milwaukee, Wisconsin

Radiation Physics course - Marquette University,
Wisconsin

Radiation Safety Officer - Medical X-Ray Center
1952 - present

He is responsible for training and performance of all personnel handling materials. He checks film badge reports weekly. Obtains services of certified radiation physicist to monitor radiation levels at least yearly.

DONALD W. BREIT, M.D.
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FORM AEC-313

Item 13

One location is used and is equipped with:

- 1) Remote handling equipment, such as remote vacuum pipette for withdrawal of liquid materials.
- 2) Shielding is provided with lead walls 2" thick, 18" wide, 18" long, 13" high, with $\frac{1}{2}$ " lead base measuring 25" x 18". (See explanatory sketch)

This is a basement, corner location with concrete walls, and earth beyond. Exposed film storage (old) is also used to occupy floor space in front of the work area. Storage area is a concrete vault measuring 24" wide, 36" long, 36" high, with the access area directed to the outside wall. This allows the storage area a 12" concrete protective barrier at the work area (see explanatory sketch). This area is assigned as receipt of materials, storage and preparation. An electric ventilating system is installed in the ceiling of this area.

Item 14

- A) Procedure for ordering materials is via telephone to Mallinckrodt Nuclear. This is coordinated with arrival date of patients. Materials are always delivered on normal work days and hours by commercial delivery system. Upon delivery, trained personnel receipt and accept the materials.
- B) The package is inspected for damage and radiation survey is made for possible spill or leaks. The container label is then carefully checked and recorded for the proper amount and assay date. This insures that possession limit is not exceeded. This procedure is carried out by trained personnel only with gloves and coats. All materials are delivered to one specific location (see sketch) where the trained personnel monitor the package. Records are maintained regarding amount received, date, monitoring results, etc.
- C) Training - Personnel

One nuclear technician - trained in handling all materials used. Formal training housekeeping personnel are not subjected to materials handling and entirely avoid the storage area. All materials are stored in vault when not in use.

(Continued)

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RADIOLOGISTS

(Continued - Item 14)

D) I. Use of all materials is strictly controlled by the Physician Radiologist.

II. Personnel (1) observe the instructions (posted) regarding wearing apparel such as coats, disposable gloves and remote handling equipment.

III. Personnel (1) does monitor the hands following each procedure and preparation.

IV. Syringe shield is used for preparation and administration of P-32. (used only 2 or 3 cases per year)

V. Clear procedural instructions are followed concerning movement of materials with remote handling equipment, etc.

VI. Materials, I-131 and P-32, are stored in vault with labels and radioactive signs until preparation is necessary, or storage for decay to permissible activity. No large amounts are ever received or stored in this facility.

VII. Personnel monitoring devices are readily available. Film badge service is used and reports available to personnel, monthly.

VIII. Waste disposal is clearly defined and observed. Short lived liquid materials that are remaining and unused are stored for decay to permissible activity before disposed.

IX. Contamination procedure is clearly described and involves the physician radiologist and also the physician radiation safety officer.

Item 15

Materials, always in small amounts, are disposed of by storage, in vault, for decay to permissible activity. When the activity is surveyed or shows only air background radiation, disposal is carried out with proper records, through garbage service.

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BYPRODUCT MATERIAL LICENSE

Amendment No. 03

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 32, 33, 34, and 35, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below; and to use such byproduct material for the purpose(s) and at the place(s) designated below. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, and is subject to all applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

| | | |
|---|---|--|
| <p>Licensee</p> <p>1. Medical X-Ray Center</p> <p>2. 1417 South Minnesota Avenue Sioux Falls, South Dakota 57105</p> | | <p>In accordance with letter dated November 15, 1972,</p> <p>3. License number 40-01493-02 is amended in its entirety to read as follows:</p> <p>4. Expiration date January 31, 1978</p> <p>5. Reference No.</p> |
| <p>6. Byproduct material (element and mass number)</p> <p>A. Iodine 131 B. Phosphorus 32</p> | <p>7. Chemical and/or physical form</p> <p>A. Iodide B. Soluble phosphate</p> | <p>8. Maximum amount of radioactivity which licensee may possess at any one time</p> <p>A. 100 millicuries B. 12 millicuries</p> |
| <p>9. Authorized use</p> <p>A. Treatment of hyperthyroidism, and cardiac dysfunction. Diagnosis of thyroid function. B. Treatment of polycythemia vera.</p> | | |

CONDITIONS

10. Byproduct material shall be used only at the licensee's address stated in Item 2 above.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation."
12. Byproduct material shall be used by Donald H. Breit, M.D., Robert P. DeClark, M.D., or Leland J. Larson.
13. Except as otherwise specifically provided by this license, byproduct material to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and nonpyrogenicity.

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NUMBER OF PAGES:

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ACCESSION NUMBER(S):

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