34-1197-1

ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

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

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.)

Lakewood Hospital
14519 Detroit Ave., Lakewood, Ohio

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

Same

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Nuclear Medicine

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

William J. Fayen, M.D.

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

(Jack Krohmer, Radiation Physicist- Consultant)

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)

None

BYPRODUCT MATERIAL OR IRRADIATION SERVICE DESIRED

6. BYPRODUCT MATERIAL (Element and mass number)		7. CHEMICAL AND PHYSICAL FORM (Or number) (6706) (6766)	8. MAXIMUM AMOUNT OF RADIOACTIVITY IN MILLICURIES THAT YOU WILL POSSESS AT ANY ONE TIME
A. I-131	Abbott	Sterile soln. or Radiocaps	100 mc. & 10 mc. respe
I-131	Abbott	Sterile soln. RISA (6703)	2 mc.
B. P-32	Abbott	Sterile soln. (6710)	50 mc.

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

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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.)

A. Diagnosis of thyroid function and treatment of hyperthyroidism and cardiac states.
Determination of blood volume.
B. Treatment of polycythemia vera and leukemia.

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

All materials will be secured in assayed forms in amounts necessary for not more than 2-3 weeks work. Handling will be done in Propipette remote pipette when indicated or radioisotope syringe. Material stored behind 2" lead shield and/or lead portable shielding. Locked and labeled space for segregating any residues or contaminated equipment.

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.

Lakewood Hospital, Lakewood, Ohio
Applicant named in Item 1

State of Ohio
County of Cuyahoga
Subscribed and sworn to before me this 21 day of September

Notary Public

MARY K. McGUIRE
NOTARY PUBLIC
CUYAHOGA COUNTY
My Commission Expires July 14, 1958

By [signature]
Chairman Isotope Committee
Title of Certifying Official

September 21, 1956
Date

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.

(Continued on reverse side)

Form AEC-313

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	Crile V.A.Hosp. Cleveland, Ohio	6 months part time	(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	"	"	(Yes) No	Yes (No)
5. Actual use of radioisotopes in the types and quantities for which application is being made, or equivalent experience	Crile V.A. Hosp. Cleveland Clinic	6 months, [illegible] 4 months, part time	(Yes) No	Yes (No)

13. ISOTOPE HANDLING EXPERIENCE

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-131	50-100 mc.	see above	see above	see 10-A

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)
SC-33A Tracerlab Scaler	1	-			Measuring
P-20AM " Scint. Probe	1	gamma	microcurie		Measuring
P-20AW " Well Count.	1	gamma	microcurie		Measuring

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

Portable laboratory monitor (Jordan AGB-10K-SR) having range from 0.01 mr/hr. to 10,000 r/hr. suitable for detecting contamination and approximate calibration.
Pocket dosimeter(Victoreen 541/A) for use laboratory personnel.

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

Calibrations checked by use standardized supplies secured as above.
Pocket dosimeters charged weekly and calibrated at two year intervals by manufacturer.

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

Propipette remote pipette for amounts of mc potency.
Abbott Radiotope syringe for P-32.
Stainless steel tray to protect lab tables.
Mobile isotope cart with 2" lead shield.

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

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

Laboratory monitored at end of each working period or as needed.
Unused portions stored in original shipping containers and/or behind 2" lead shield.

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1a. Training and Experience With Radioactivity of Radiological Safety Officer

Credentials for Mr. Jack Krohmer, Certified Radiological Physicist, are on file with the Atomic Energy Commission.

The Medical Staff of Lakewood Hospital has placed Dr. T. W. Knickerbocker, Radiologist, in charge of radiological safety throughout the hospital, through consultation with Mr. Krohmer.

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Form AEC-313a (3/56)

ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE—PAGE 1

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

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 & 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 Supplement A—Human Use—Page 3 (statement of using physician's clinical radioisotope experience) is submitted in support of this application. If answer is NO, use reverse side of this page 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 reverse side if necessary).

I-131 Diagnosis of thyroid function and blood volume and treatment of hyperthyroidism and heart conditions.

P-32 Treatment of polycythemia vera and leukemia.

(b) Chemical form administered:

I-131 Abbott sterile soln. or Radiocaps; Iodinated serum albumin(RISA)
P-32 Abbott sterile soln.

(c) Describe procedures which will be observed to minimize hazard from handling, storage, and disposal of the byproduct material:

Propipette remote pipette for mc. potency. Abbott Radiotope syringe. Mobile isotope cart with 2" lead shield. Unused amounts stored in shipping containers and/or behind lead shield. Stainless steel tray. Portable lab monitor. Pocket dosimeters.

(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)

PROPOSED DOSAGE SCHEDULE

5. (a) In millicuries for internally administered byproduct material other than discrete fixed source, 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 fuse reverse side if necessary):

I-131 Hyperthyroidism- 2 to 40 mc.
Cardiac states 10 to 50 mc.

P-32 Leukemia 2 to 10 mc.(Av. 2-5)
Polycythemia vera 2 to 10 mc.(Av. 2-5)

(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, and 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:

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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

3. Preceptors Statements from Dr. Penn Skillern, Cleveland Clinic and Dr. Reginald Shipley, Crile V.A. Hospital, Cleveland, Ohio on file with Commission.

5 (a). The amounts indicated in the Proposed Dosage Schedule are for single doses, with repeat treatment dictated by clinical followup.

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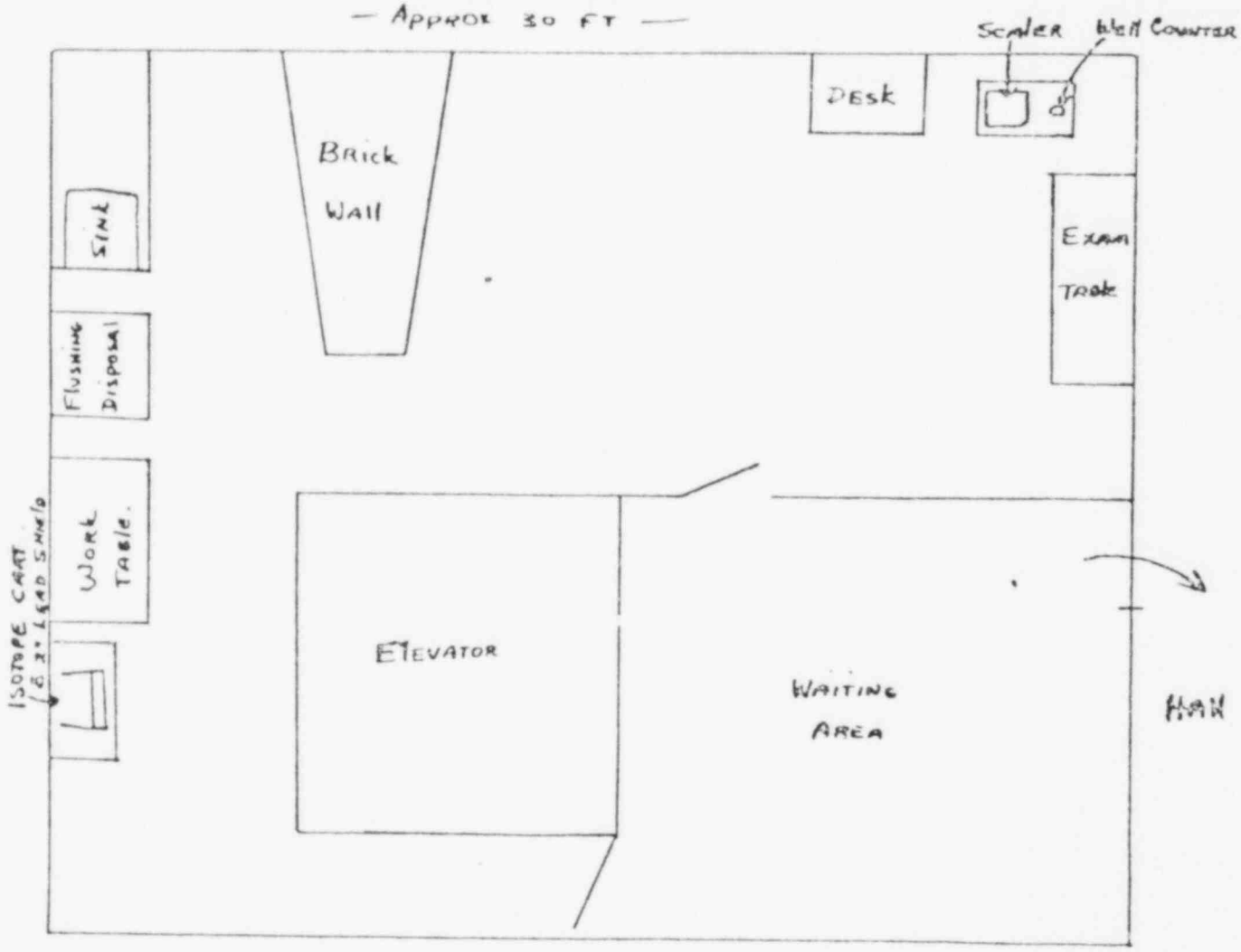
SKETCH OF LABORATORY FACILITIES



RADIOISOTOPES COMMITTEE file

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LAKEWOOD HOSPITAL
14519 Detroit Ave.
Lakewood, Ohio

1. Members of the Committee

   a. Thomas W. Knickerbocker, M. D., Chief, Division of Radiology - Chairman

   b. James T. Ledman, M. D., Chief, Division of Medicine

   c. Helen R. Cash, M. D., Board Qualified in Internal Medicine

   d. Oliver Eitzen, M. D., Chief, Division of Pathology

2. Duties of the Committee

   a. Supervise the establishment and operation of the Radioisotopes Laboratory, including the selection of equipment.

   b. Review and grant permission for, or disapprove, the use of radioisotopes within the institution from the standpoint of radiological health safety.

   c. Prescribe special conditions which may be necessary, such as physical examinations, additional training, designation of limited area of use, and disposal methods.

   d. Review records and receive reports from the radiological safety officer.

   e. Recommend remedial action when a person fails to observe safety recommendations and rules.

   f. Keep a record of actions taken by the Committee.

3. Miscellaneous

   a. Mr. Jack Krohmer, Certified Radiological Physicist, acts in consulting capacity to the Committee.

   b. William J. Fayen, M. D., the using physician, may attend meetings of the Committee.

Lakewood Hospital
~~Department of~~
14519 Detroit Ave.
Lakewood, Ohio

Med. Isotope Comm file
Return to Levy

INSTRUCTIONS FOR NURSES REGARDING USE OF RADIOACTIVE ISOTOPES

The great majority of radioactive procedures consist of radioiodine uptakes by the thyroid. Here the dose is extremely small and there is no radiation problem.

For patients receiving the much larger doses of radioiodine therapy, the floors will receive special orders, including safety precautions. These include:

1. Notice of the recent administration of a radioactive substance should be placed on the patient's bed.

2. Rubber or plastic mattress protection should be used.

3. Patients may use patient lavatories, being careful to flush toilets.

4. If using bedpan because of bed confinement, rubber gloves must be used by personnel handling pans containing urine. Spillage must be avoided. Pans must be rinsed three times after being emptied of contents. Soiled gloves must be similarly rinsed.

5. If incontinent of urine, an indwelling catheter must be used and care taken in discarding the urine. Collection bottles must be rinsed three times before being used for other patients. Catheters and tubing must be rinsed well after using and sent to the Radioisotope Laboratory before discard.

6. If patient wets bed clothes, they should be removed from bed with rubber gloves and sent to the Radioisotope Laboratory.

7. If the patient receives 30 millicuries or more:

   a. Personnel should not spend over one hour a day per person in immediate vicinity of the patient's thyroid gland for one week.

   b. Nursing staff will be notified of such dosage.

8. Private rooms are not necessary.

9. Visitors are not limited. Precautions should be taken as with nurses for doses of 30 mc. or over.

No precautions are necessary in cases of radiophosphorus (P-32) therapy.

In case of death in less than two weeks after isotope therapy or any question of handling or contamination, contact Dr. Thomas W. Knickerbocker or Dr. William J. Fayen.