

UNITED STATES ATOMIC ENERGY COMMISSION
APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved
Budget Bureau No. 38-R0027

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.)

Harvey Jack Lerner, M.D.
829 Spruce Street, Room 407
Philadelphia, PA 19107

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

700 Spruce Street
Philadelphia, PA 19107

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Surgical Research

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

37-13728-01

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.)

H. J. Lerner, 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.)

J. W. Birkbeck
(See Attachment #2)

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

C-14

(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.)

C-14 labeled procaine Amide
E. R. Squibb & Sons, Inc.

2 millicuries

H-3

H-3 labeled Hydroxy Urea
E. R. Squibb & Sons, Inc.

2 millicuries

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.)

Materials to be used as part of a chemo-therapeutic research project. The items listed in part 6 will be instilled directly into the bladders of the test animals (dogs). The material and urine will then be withdrawn, packaged in containers and returned to Squibb for counting and disposal.

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REG1 LIC30
37-13728-01 PDR

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	E. R. Squibb & Sons, Inc. New Brunswick, New Jersey	3 day	Yes No	<input checked="" type="radio"/> Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	E. R. Squibb & Sons, Inc. New Brunswick, New Jersey	Course	Yes No	<input checked="" type="radio"/> Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity	E. R. Squibb & Sons, Inc. New Brunswick, New Jersey		Yes No	<input checked="" type="radio"/> Yes No
d. Biological effects of radiation			Yes No	Yes No

9. EXPERIENCE WITH RADIATION (Actual use of radionuclides or equivalent experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
14 C	50 uCi	Pennsylvania Hospital Philadelphia, PA	1 year	As described in section 7 of this application.

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)
Baird Atomic Rate Meter & GM Tube	1	β γ	1000mr/hr.	unknown	Monitoring & Survey
C.D. Type Survey Meter	1	β γ	1000mr/hr.	unknown	Monitoring & Survey

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

Prior to each survey using instrument circuit and ¹³⁷Cs Standard Source.

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

Film badges by Landauer

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

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.

License Fee Category \$ _____

Applicant named in item 1

Fee Enclosed \$ _____

By: _____

Date _____

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.

RADIATION PROTECTION PROGRAM
Sections 13, 14, 15

1. When not in use radioactive materials will be stored in original shipping containers.
2. Radioactive materials will be stored in an area away from working and transient personnel.
3. Radioactive materials for disposal will be returned to supplier in original containers and in compliance with the Department of Transportation Regulations for radioactive materials.
4. When handling radioactive materials personnel will take advantage of time, distance, and shielding as a means of keeping radiation exposure to a minimum.
5. Animals used during experiments will be housed in separate cages clearly marked with a radioactive area identification sign.
6. Urines will be collected for 24 hours following each experiment and monitored for radioactivity levels prior to disposal.
7. Urines containing radioactivity will be returned to Manufacturer (E. R. Squibb & Sons) as part of the experiment for measurements and disposal.
8. Upon completion of each experiment, area of use will be surveyed.
9. Areas of contamination will be immediately decontaminated in the prescribed manner.
10. Ancillary personnel will be monitored and instructed in the safe handling of isotopes and also in good radiation protection and practice.

Harvey Jack Lerner, M.D.

Joseph W. Birkbeck
Joseph W. Birkbeck

TRAINING AND EXPERIENCE OF INDIVIDUAL NAMED IN ITEM 5

8. Type of Training

- a. Principles and Practices of Radiation Protection
- b. Radioactivity Measurements Standardization and monitoring Techniques and Instruments.
- c. Mathematics and Calculation to the Use and Measurement of Radioactivity.

All of the above are included in the following Experience, Training, and Education Programs:


4 years University of Scranton
B.S. Major Biology 1947-1951

1 Semester St. Joseph College
Phila. Radioisotope Methodology 1964

1 year (2 Semesters) Hahnemann Hospital
Clinical Nuclear Medicine 1963-1964

2 week Phila. College Pharmacy and Science
Principals of Radioimmunoassay 1974

12 years E. R. Squibb Experience and In House
Training in Nuclear Medicine 1963-1974


J. W. Birkbeck



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
631 PARK AVENUE
KING OF PRUSSIA, PENNSYLVANIA 19406

FEB 04 1985

(215) 337-1150

Docket No. 030-03200
Inquiry No. 85-01

License No. 37-13728-01
Expiration Date: July 31, 1980

Harvey Jack Lerner, M.D.
ATTN: Ms. Marie DiRenzo
Administrative Assistant
330 South 9th Street
Philadelphia, Pennsylvania 19107

Gentlemen:

Subject: NOTICE OF EXPIRED LICENSE

This refers to the telephone discussion between Mrs. Marlene J. Taylor of this office and Ms. DiRenzo of your staff on January 11, 1985. The subject of the discussion was the fact that NRC records show that the license identified above has expired and no renewal application has been filed in accordance with Section 30.37 of Title 10, Code of Federal Regulations, Part 30.

From this discussion we learned that you do not have any licensed material in your possession. Therefore, you must take the following actions:

1. Prepare a statement which explains the method of disposal of the materials, including: what material was involved, how it was disposed of or to who it was shipped, and when this was done. The enclosed Form NRC-314 may be used for this purpose.
2. If the activities conducted under the expired license were subject to the reporting requirements of 10 CFR Part 20, Section 20.407, you must submit the annual report required by 20.407 for the current calendar year and a termination report required by Section 20.408 for individuals engaged in activities under the expired license. Those reports must be submitted to the Director of Management and Program Analysis, U. S. Nuclear Regulatory Commission, Washington, D.C. 20555.

You are required to reply to this Notice within 30 days of the date above. Address your reply to Region I, U. S. Nuclear Regulatory Commission, Attention: Chief, Nuclear Materials Section A, 631 Park Avenue, King of Prussia, Pennsylvania 19406.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

The responses directed by this Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

85-4117-213

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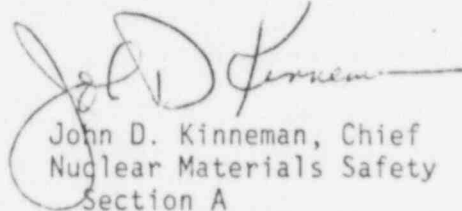
FEB 04 1985

Harvey Jack Lerner, M.D.

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We request that you give prompt attention to these matters. Should you have any questions regarding them, we would be pleased to discuss them with you.

Sincerely,

A handwritten signature in dark ink, appearing to read "J. D. Kinneman", is written over the typed name and title.

John D. Kinneman, Chief
Nuclear Materials Safety
Section A
Division of Radiation Safety
and Safeguards

Enclosure: NRC Form 314

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania