

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item):

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 20-18423-01
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Eunice Kennedy Shriver Center for
Mental Retardation, Inc.
200 Trapelo Road
Waltham, MA 02254

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED:

Eunice Kennedy Shriver Center for Mental Retardation, Inc.
200 Trapelo Road
Waltham, MA 02254

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Robert H. McCluer, Ph.D.

TELEPHONE NUMBER

(617) 642-0135

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

AMOUNT ENCLOSURE \$ 120.00

13. CERTIFICATION (Must be completed by applicant): THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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.

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

Robert H. McCluer

Robert H. McCluer

DIRECTOR Biochemistry
Radiation Safety Officer 10/17/85

14. VOLUNTARY ECONOMIC DATA

ANNUAL RECEIPTS	
< \$250K	\$1M - 3.5M
\$250K - 500K	\$3.5M - 7M
\$500K - 750K	\$7M - 10M
\$750K - 1M	> \$10M

d. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

c. NUMBER OF BEDS

15. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)

☐ YES

☐ NO

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

“OFFICIAL RECORD COPY”

APPROVED BY

DATE

AMOUNT RECEIVED

CHECK NUMBER

MI 1A

104531

ITEM 5. Radioactive Material

<u>By-Product, Source and/or Special Nuclear Material</u>	<u>Form</u>	<u>Maximum Amount</u>
Iodine - 125	Any	4 mCi

ITEM 6. Purposes for which licensed material will be used

Iodination of proteins for use in radioimmunoassays and in vitro biochemical studies.

ITEM 8. Training for people working in or frequenting restricted areas

- A. Please delete Wayne Miller, M.D. from the list of supervisors.
- B. Please add Jean Amos, Ph.D. to our list of supervisors and users:
- C. Please include 125I to the list of radionuclides used by Dr. Marjorie Lees

1. Training

	<u>Course</u>	<u>Duration</u>	<u>On the Job</u>	<u>Formal</u>
Jean Amos, Ph.D.	MGH Radiation Safety 1981	4 wks.	Yes	Yes
Marjorie Lees, Ph.D.	Harvard Radiation Safety	2 wks.	Yes	Yes

2. Experience Radionuclide

Jean Amos, Ph.D.			
14C	MGH	3 yrs.	Synthesis Labelled Cpds
3H	MGH	3 yrs.	Synthesis Labelled Cpds
32P	EKS	5 yrs.	Synthesis Labelled Cpds
125I	EKS	1 yr.	Radioimmunoassays
Marjorie Lees, Ph.D.			
14C	McLean	5 yrs.	Research
3H	McLean	5 yrs.	Research

ITEM 9. Facilities and Equipment

The procedure for labelling proteins will be carried using either a volatile form of 125I such as NaI or a non-volatile form such as sufanilic acid.

One to two mCi amounts of these 125I compounds will be used for the iodinations. All procedures will be carried out in a fume hood, exclusively designated for this purpose. The air flow in this hood averages 150-160 linear feet per minute.

All precautions will be followed, as outlined on pages 5-8 of our regulations for the use of radionuclide at EKS for Mental Retardation, Inc.

Please find these precautions enclosed as Appendix II.

It will be necessary to perform these iodinations approximately once every two months. When volatile ^{125}I is used, Harvard Environmental Health personnel will install an air filter pump in the hood to monitor the release of ^{125}I to the environment. Harvard will also provide thyroid scans for personnel performing the iodinations, both before and after the procedure. Enclosed as Appendix III please find a confirmation letter from Harvard Environmental Health stating that the appropriate measures for monitoring the environment and personnel will be taken, and that our facilities for handling volatile iodine are adequate.

APPENDIX I

MATERIALS LICENSE

Amendment No. 02

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Eunice Kennedy Shriver Center
for Mental Retardation, Inc.

2. 200 Trapelo Road
Waltham, Massachusetts 02254

In accordance with application dated
April 12, 1985

3. License number 20-18423-01 is amended in its
entirety to read as follows:

4. Expiration date June 30, 1990

5. Docket or
Reference No. 030-15057/20-18423-02

6. Byproduct, source, and/or
special nuclear material

7. Chemical and/or physical
form

8. Maximum amount that licensee
may possess at any one time
under this license

A. Hydrogen 3
B. Carbon 14
C. Sulfur
D. Phosphorus 32
E. Iodine 125
F. Potassium 42
G. Chlorine 36
H. Calcium 45

A. Any
B. Any
C. Any
D. Any
E. ~~Protein bound~~ ANY
F. Any
G. Any
H. Any

A. 2 curies
B. 100 millicuries
C. 100 millicuries
D. 35 millicuries
E. 2 millicuries ✓ 4 millicurie
F. 0.2 millicuries
G. 0.2 millicuries
H. 5 millicuries

9. Authorized use

A. through H. Research and Development as defined in 10 CFR 30.4(q); animal studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities, 200 Trapelo Road, Waltham, Massachusetts.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions, and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."

~~8507250028~~

11 pp.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

Docket or Reference number

20-18423-01

030-15057/20-18423-02

Amendment No. 02

(continued)

CONDITIONS

12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Edwin Kolodny, M.D.	H-3, C-14, S-35, and Ca-45
Robert H. McCluer, Ph.D.	All
Peter Daniel, Ph.D.	All
Verne Caviness, Jr., M.D.	H-3, C-14, S-35 and Ca-45
Kathleen Rockland, Ph.D.	H-3, C-14, S-35, Ca-45 and I-125
Srinivasa Raghavan, Ph.D.	All
Xandra Breakefield, Ph.D.	All
Tom Fox, Ph.D.	All
Firoze Jungalwala, Ph.D.	All
Victor Sapirstein, Ph.D.	All
Gerald A. Schwarting, Ph.D.	H-3, C-14, S-35, Ca-45 and I-125
Wayne Miller, M.D.	H-3, C-14, S-35, Ca-45 and I-125
Leu-Fen Lin, Ph.D.	H-3, C-14, S-35 and Ca-45
Marjorie Lees, Ph.D.	H-3, C-14, S-35 and Ca-45, I-125
JEAN AMOS, Ph.D.	All

13. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.
14. Experimental animals administered licensed materials or their products shall not be used for human consumption.
15. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated April 12, 1985 and letter dated June 12, 1985. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By Jenny M. Johanson

Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406

JUN 25 1985

APPENDIX II

over whom he/she has supervision, and to locations under his/her control;

4. keep current working records of the receipt and disposition of radionuclides in his/her possession including use in research, waste disposal, transfer, storage, etc.;
5. notify the RSO of any personnel changes and changes in rooms or areas in which radioactive materials may be used or stored;
6. keep an adequate inventory of the amount of radioactive material possessed. Inventory will be checked and updated monthly;
7. post rules and instructions pertinent to laboratory operations as requested by the RSO;
8. insure that a survey meter is available to enable personnel to monitor for radiation exposure and surface contamination for radionuclides other than tritium;

A refresher course will be given annually to review regulations and procedures. This is mandatory for all personnel working with radioactive materials.

6. Work Habits and Procedures:

6.1 Preparatory:

Before any work is undertaken with quantities of radionuclides which have potential for producing significant exposure, attention should be given to precautionary measures including the use of hoods, adequacy of the hood, air monitoring, respiratory protection, etc.

For non routine or high level operations, the user will conduct a "dry run" with inactive or low level activity to test the adequacy of procedures and equipment.

6.2 Protective Clothing:

Suitable gloves must be worn whenever hand contamination is likely. Extreme care must be exercised to prevent contamination when there is a break in the skin.

Appropriate protective clothing ie., lab coats, aprons, must be worn whenever working with radioactive materials. Protective clothing must not be worn or taken out of the restricted area, unless monitored and determined to be free of contamination.

6.3 Handling Materials:

All work areas, bench tops and hoods should first be covered with protective absorbent material before beginning to work. Work which can result in contamination of bench top or other work surfaces should be done using trays lined with protective absorbent material.

6.4 Hygiene:

Personnel working in areas containing radioactive materials must "wash up" before eating, smoking, or leaving work and shall use proper monitoring equipment to make hand and shoe counts upon completing operations.

Eating, storing or preparing food is forbidden in restricted laboratory areas.

Radioactive liquids shall not be pipetted by mouth.

Smoking in the laboratories is not permitted.

All restricted areas will be secured and locked at the end of each working day.

7. Use of Radioactive Materials in Laboratory Animals:

Injections of radioactive material into laboratory animals should be performed in the restricted area of the principal investigator. All procedures must be short-term (24-48 hr). Appropriate measures, such as the use of protective absorbent material for the work area and the animal cages must be followed.

Cages housing the injected animals must be clearly labelled as to the radionuclide used, quantity injected per animal, date of injection and user. These animals are to be kept in the restricted lab area in or near the fume hood. At no time will these animals be returned to the regular animal care facility.

Animal excreta, the cage liner, and other solid waste should be placed in heavy duty plastic bags, appropriately labelled and disposed. The animal carcass, likewise, should be sealed in a plastic bag, appropriately labelled and stored in the designated freezer until disposal.

Animal handlers must be advised by the principal investigator as to the dose levels, time limitations in the area, and the handling requirements of the animals and excreta.

Animal cages must be completely decontaminated following use. This decontamination will take place only in a designated "hot sink" area. Following decontamination procedures, appropriate wipe tests and surveys will be made before cages are returned to the animal care facility.

8. Regulations Regarding the Use of 32P, 3H, 125I

In addition to the standard procedures for radionuclide use, set forth in Section 6 page 5, the following additional precautions used when working with 32P, 125I, and millicurie amounts of 3H.

8.1 Regulations for Handling 32P and 125I:

- a. Employ low and high density shielding (low density ie.,

plexiglass, lucite etc. near the source). Use of a lead apron or additional protective clothing; Use of protective mask when working with volatile ^{125}I .

- b. Protection of eyes from chemical splash and unnecessary radiation. Personnel working with 1 mCi or more must wear safety glasses.
- c. Use a double layer of gloves, the inner gloves should remain uncontaminated.
- d. All personnel must wear film badges; when working with 1mCi or more ring badges must also be worn.
- e. A survey meter must be in the area.
- f. All work with volatile ^{125}I (protein iodinations) must be carried out in a fume hood. Air flow must be checked prior to beginning work.

For processes requiring the use of 1mCi or more of ^{32}P or protein bound ^{125}I , work should be carried out in a fume hood.

- g. Vials containing ^{32}P or ^{125}I should be open for as brief a time as necessary and tightly capped when not in use.

Vials should be stored in lead shielded containers, which are clearly labelled as to radionuclide, quantity and date.

- h. After each day's use, wipe tests and surveys of the area, protective clothing and extremities are required. Area should be cleaned.

If skin contamination is detected, wash immediately with soap and plenty of water.

- i. Isolate waste and dispose promptly.

- j. For non-routine or high level procedures

1. Notify RSO
2. Describe procedures and precautions
3. Discuss the need for bioassays
 - a. See Table 3. of Appendix I
 - b. Baseline ... pre-operation bioassay
 - c. thyroid scan ^{125}I
4. Perform "dry run" to insure there will be no unexpected complications and to insure equipment is functioning properly.

8.2 Bioassays ^{125}I ^{32}P

- a. Submission of urine samples on a regular basis for personnel working with mCi amounts of ^{32}P ; samples should be submitted within 12 hours after working with this radionuclide.
- b. Personnel working with mCi amounts of ^{125}I should have pre-operation baseline bioassay of thyroid and have routine testing throughout the operation.

8.3 Spills...125I ...32P

There are radiation decontamination kits available in the Biochemistry Department. All personnel should be notified as to the storage location of these kits.

a. 32P < 1mCi

1. inside hood - clean immediately before proceeding;
2. outside hood - isolate area, clean and decontaminate, notify RSO, confirmation that area is free of contamination is necessary before proceeding;

b. 32P > 1mCi

1. inside hood
hood should be sealed; RSO must be notified;
use absorbent materials and proceed with decontamination under the direct supervision of the RSO;
2. outside hood
isolate area; check for personnel contamination;
notify the RSO; evacuate area; proceed with decontamination with the advice of the RSO and Harvard Environmental Health and Safety.

c. 125I

1. decontaminate surface with a solution of 0.1M NaI, 0.1M NaOH, 0.1M Sodium thiosulfate; this solution will help to stabilize the material and minimize the evolution of volatile species;
2. all liquid waste must be absorbed;
3. proceed with a decontaminate or detergent to complete the the clean-up;
4. NEVER ADD ACIDS TO RADIOIODINE SOLUTIONS!

8.4 3H Compounds

- a. Personnel working with mCi amounts of 3H radionuclides are required to perform all operations in a fume hood;
- b. All precautions listed on page 5 apply;
- c. Bioassays

Personnel planning to work with quantities in excess of those listed in Table 3, Appendix I should notify the RSO;

1. All personnel in the restricted area should submit bioassay samples prior to beginning work;
2. Routine submission of samples, thereafter, at 2 week intervals until the work is complete;
3. Final samples should be submitted within 10 days of the final

APPENDIX III

HARVARD UNIVERSITY
UNIVERSITY HEALTH SERVICES
ENVIRONMENTAL HEALTH AND SAFETY

46 Oxford Street
Cambridge, Massachusetts 02138
(617) 495-2061

October 9, 1985

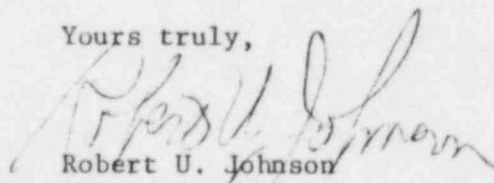
Ms. Marcia Williams
Dept. of Biochemistry
Eunice Kennedy Shriver Center
200 Trapelo Road
Waltham, MA 02154

Dear Ms. Williams:

In response to our telephone conversation regarding the amendment to your Nuclear Regulatory Commission license, we have made arrangements to monitor the iodinations for any potential release of airborne activity to the environment. I understand that these iodinations will be carried out in the hood which I measured for its air flow and found that the flow rate met the specifications for any iodination. With regards to the monitoring, three days notice must be given to my staff in order that the scheduling can be mutually arranged. I have also discussed the iodinations with Dr. Jean Amos who will be performing them regarding the iodination procedures, personal protection, handling of the waste material, and the requirement that thyroid measurements must be made after each iodination.

If there are any further questions, please feel free to contact me at any time.

Yours truly,



Robert U. Johnson
Director
Radiological Services

RUJ:dp

BETWEEN: William D. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED Eunice Kennedy Shriver Center

Applicant/Licensee: For Mental Retardation, Inc

Application Dated: 10/17/85

Control No.: 104531

License No.: 20-18423-01

2. FEE ATTACHED

Amount: \$ 120.00

Check No.: 8301

3. COMMENTS

03/20
6/90

Signed Brenda Platchk

Date 10/23/85

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3M (\$120)

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal _____

License _____

Signed J. Jackson

Date 11/9/85

In settlement of the following invoices:			
DATE	AMOUNT		
TOTAL OF INVOICES			
LESS % DISCOUNT			
LESS			
TOTAL DEDUCTIONS			
AMOUNT OF CHECK			

EUNICE KENNEDY SHRIVER CENTER FOR
MENTAL RETARDATION, INC.
 200 TRAPELO ROAD
 WALTHAM, MASSACHUSETTS 02154

No. **8301**

5-13 110

PAY TO THE ORDER OF October 4 1985 U.S. Nuclear Regulatory Commission \$ 120.00

PAY TO THE ORDER OF

DOLLARS

BANK OF NEW ENGLAND, N.A.
 BOSTON, MASSACHUSETTS

TWO SIGNATURES REQUIRED AT ALL TIMES

Edwin H. Kebede

[Signature]

⑈00830⑈ ⑆011000138⑆ 2477⑈0786⑈

"SECTION COPY"