

APPLICATION FOR MATERIAL LICENSE

L&L 28214

030-30601

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS 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 HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
 NUCLEAR MATERIALS SAFETY 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
 NUCLEAR MATERIALS SAFETY 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
 NUCLEAR MATERIALS SAFETY SECTION
 1460 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.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input checked="" type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)</p> <p>Paul Reiss MilliGen 75 Wiggins Avenue Bedford, MA 01730</p>
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3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

MilliGen
 75 Wiggins Avenue
 Bedford, MA 01730

8912060244 880915
 REG1 LIC30
 20-28214-01 PDR

<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>Paul Reiss</p>	<p>TELEPHONE NUMBER</p> <p>617-275-5208-X-2312</p>
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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.

<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>
<p>9. FACILITIES AND EQUIPMENT.</p>	<p>10. RADIATION SAFETY PROGRAM.</p>
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)</p> <p>FEE CATEGORY 3M AMOUNT ENCLOSED \$ 460.000</p>

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, 36, 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	DATE
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14. VOLUNTARY ECONOMIC DATA											
<p>a. ANNUAL RECEIPTS</p> <table border="1"> <tr><td><\$250K</td><td>\$1M-3.5M</td></tr> <tr><td>\$250K-500K</td><td>\$3.5M-7M</td></tr> <tr><td>\$500K-750K</td><td>\$7M-10M</td></tr> <tr><td>\$750K-1M</td><td>>\$10M</td></tr> </table>	<\$250K	\$1M-3.5M	\$250K-500K	\$3.5M-7M	\$500K-750K	\$7M-10M	\$750K-1M	>\$10M	<p>d. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)</p> <p>e. NUMBER OF BEDS</p>	<p>d. 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)</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>	
<\$250K	\$1M-3.5M										
\$250K-500K	\$3.5M-7M										
\$500K-750K	\$7M-10M										
\$750K-1M	>\$10M										

FOR NRC USE ONLY			
TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS
APP	May 21 st	3M	
AMOUNT RECEIVED	CHECK NUMBER	APPROVED BY	
\$460 ⁺ / 240	008307/6374	S. Kimbrell	
		DATE May 6/2/88	
		108918	

"OFFICIAL RECORD COPY"

5/16/88

May 2, 1988

Jenny Johansen
U.S. Nuclear Regulatory Commission, Region I
Nuclear Material Section B
631 Park Avenue
King of Prussia, PA 19406

Dear Ms. Johansen;

Enclosed is an application for a new Material License and the appropriate license fee.

Please confirm receipt of this application and contact me if you should have any questions.

Sincerely,

MilliGen, Div. of Millipore

Paul D. Reiss, RSO

PDR/kc
Enclosure

Radioactive Materials

<u>Element and Mass No.</u>	<u>Chemical and/or Physical Form</u>	<u>Maximum amount Possessed at any One Time</u>
Iodine-125	125-I labeled protiens	5mCi
Hydrogen-3	3-H labeled amino acids, proteins, nucleotides, nucleic acids and other organic molecules	50mCi
Carbon-14	14-C labeled amino acids, proteins, nucleotides, nucleic acids and other organic molecules	25mCi
Phosphorus-32	32-P labeled inorganic phosphate, nucleotides, nucleic acids, amino acids, proteins and other organic molecules	50mCi
Sulfur-35	35-S labeled nucleic acids nucleotides, amino acids, proteins and other organic molecules	50mCi

ITEM 6

Purpose For Which Licensed Material Will Be Used

Iodine-125

Research use of tracer quantities. Iodinated material will be used to study antigen-antibody interactions and the absorption of iodinated proteins and polypeptides to surfaces such as ultra-filtration membranes.

Hydrogen-3

Carbon-14

Sulfur-35

Phosphorus-32

Research use of tracer quantities. All isotopes will be used in the areas of nucleic acid and protein chemistry, and biochemistry. Typical assays will include Southern and Northern blot hybridization; the absorption of proteins to surfaces such as ultrafiltration membranes; sequencing of phosphorylated proteins and peptides; and the sequencing of DNA and oligonucleotide fragments following standard protocols utilizing polyacrylamide gel electrophoresis.

Date: 1979-1985
Location: National Institute on Alcohol Abuse and Alcoholism, Rockville, MD
Supervisor: Dr. Richard L. Veech
Content: Routine use of ^3H , ^{14}C , ^{32}P , and ^{45}Ca in quantities less than 200uCi for research purposes involving determination of metabolic flux in perfused liver, heart and isolated hepatocytes preparations using hplc, $^{14}\text{CO}_2$ evolution; ^{14}C and ^{32}P labeling of proteins; and the metabolism of ^{45}Ca using transmission electron microscopy and autoradiography.

Date: 1976-1979
Location: University of Maryland, College Park, MD
Supervisor: Dr. Sidney K. Pierce
Content: Routine use of ^3H and ^{14}C in quantities less than 100uCi for research purposes involving estimations of metabolic flux of amino and other organic acids in perfused tissues of marine organisms using hplc, measurement of $^{14}\text{CO}_2$, and amino acid analyses.

Date: 1976
Location: State University of New York, Stony Brook, NY
Supervisor: Dr. Eugene Katz
Content: Routine use of ^{125}I in quantities less than 2mCi for research purposes involving the iodination of membrane proteins in developing slime molds using SDS-PAGE electrophoresis.

Date: 1976

Location: Marine Biological Laboratory, Woods Hole, MA

Supervisor: Dr. Walter Vincent

Content: Routine use of ^3H and ^{14}C in quantities less than 100uCi for research purposes involving determination of metabolic flux in perfused tissues by measuring $^{14}\text{CO}_2$ evolution and in labeling protein for establishing rates of protein turnover.

Responsibilities: As primary RSO will be responsible for training all laboratory personnel as well as implimenting standard operating procedures for the handling and use of all radioactive materials. Will serve as the alternate for checking in radioactive materials, performing wipe tests, and making sure proper procedure is followed for radioactive waste removal.

David Hughes

B.S. Chemistry
University of Lowell

Course Work:

Instruction in the safe use of Radioisotopes
Harvard Medical School, 1984

Location:

Millipore Corp.
Analytical Services Dept.
Bedford, MA.

Laboratory
Experience:

Routine performance of wipe tests on GC equipment
containing radioactive material.

Responsibilities:

Primary duties will include logging in of all radio-
active materials when received, performing wipe
tests, supervising new laboratory personnel in
the proper handling of radioactive materials, and
maintaining records of inventory and disposal
of radioactive materials.

Robert U. Johnson, Millipore Consultant
Director, Radiological Services
University Health Services
Environmental Health and Safety
46 Oxford Street
Cambridge, MA 02138

Responsibilities:

Initial training of all laboratory personnel
and consultant if required.

ITEM 8

Training for Individuals Working in or Frequenting
Restricted Areas

All individuals receive copies of the MilliGen Radiation Safety Manual (currently in preparation). Laboratory personnel are required to attend the first two lectures of "Instruction in the Safe Use of Radioisotopes" given at Harvard Medical School by the Department of Environmental Health and Safety. This training will be supplemented by an annual refresher course given by the Radiation Safety Officer. Radioisotope work is taught and monitored by the Radiation Safety Officer and the individual's supervisor. The initial training of the maintenance staff and non-laboratory personnel in the proper handling of radioactive areas will be conducted by the Radiation Safety Officer. This training will be supplemented by an annual refresher course given by the RSO.

ITEM 9

Laboratory Facility:

All radioactive experiments will be carried out in the area marked 'Biology Lab'. Access to this area is limited by two locked doors. Radioactive materials will be stored in a locked freezer within the area designated as the 'Red Room'. The access to this room is limited to a locked door. This room will also be used for infrequent experiments which require the use of ^{125}I . Radioactive waste will be stored in an adjoining locked room designated as the 'Waste' room. The 'Dark Room' will be used almost exclusively for developing autoradiograms. Radioactive experiments in the 'Biology Lab' will be limited to the hood and sections of bench closest to the 'Waste room'. The names used to designate areas are only tentative as the laboratories are currently under construction.

Equipment:

<u>Type of Instrument</u>	<u>Manufacturer and Model o.</u>	<u>Radiation Detected</u>	<u>Sensitivity Range</u>
Geiger counter	Atlantic Nuclear Ludlum 3	Gamma	100-60,000cpm
Beta counter	Atlantic Nuclear	Beta	
Liquid Scintillation Counter	Micromedic 36004	Beta	70-6,000,000cpm
Gamma Counter	Micromedic 2200	Gamma	70-300,000cpm

Calibration of Equipment

A. Calibration by Service Company

Ludlum 3 Geiger counter will be calibrated at R. S. Landauer Jr. and Co., 2 Science Road, Glenwood, Illinois, 60425-1586, in accordance with NRC Lic. No. 20-00297-53 requirements.

B. Calibration By Applicant

1. The 2200 Gamma counter will be recalibrated bi-monthly when radioisotope work is being done or when sealed source simulated standard counts vary by more than 10%. When in-house re-calibrations are unsatisfactory, the Micromedic service representative is called to re-calibrate the counter. The 2200 Gamma counter calibration is checked daily when in use by counting the standards for one minute and recording the count rate and the background count rate in a log book.

In-house calibration procedure as performed by RSO:

- A. Set gain at 20% (each division then equals 1 kev)
- B. Set windows to bracketed Cs standard: A=652, B=672,
(Cs peak = 662)
- C. Put Cs std, Model NES-139s from New England Nuclear into counter.
- D. Fine tune the gain to yet maximum CPM using 0.1 minute counts and manual reset. (note: should be approx. 27.5% gain).
- E. Change windows to bracket a new range (A = 600, B= 724).
- F. Check several readings for one minute. All counts should be within 5% deviation.
- G. If counts differ by 75%, the Micromedic Company will be called to calibrate the high voltage and on repair the counter.
- H. Set windows to bracket appropriate isotope energy levels.
- I. Calculate percent efficiency of counter with commercial standard on in-house dilutions:

$$\frac{\text{cpm}}{\text{dpm}} \times 100$$

ITEM 10

Radiation Safety Program

A. Receipt of Radioactive materials: Incoming packages containing radiation shall be wipe tested in accordance with 10 CFR 20.205 as follows:

1. Outside of shipping carton
2. Inside of shipping carton
3. Outside of inner carton
4. Inside of inner carton
5. Outside of lead pig or plastic container
6. Outside of vial containing radioactivity (without breaking shrink rap)
7. Surface of vial containing radioactivity inside shrink wrap.

Procedure: A clean, moistened 4.25 am Whatman 1 filter paper is used per test. Wipes are counted for 10 minutes in the appropriate counter. If external contamination limits are exceeded (200 MR/hr at the package extension), appropriate NRC offices and the delivery carrier will be notified.

B. Storage: All incoming radioactive materials will be stored within a locked refrigerator in the area currently designated as the Red Room.

C. Facility: The Areas that will be used for conducting radioactive experiments and for the storage of radioactive materials and waste are outlined below. The RSO will see that wipe tests are done twice a month and recorded in a ledger on the following areas (see attached diagram) when radioisotope work is being done.

1. Floor in front of refrigerator
2. Hood in Red Room
3. Floor in front of hood in Red Room
4. Floor in front of Red Room
5. Floor in front of Scintillation and gamma counters
6. Scintillation counter
7. Gamma counter
8. Hood in Biology Lab
9. Floor in front of Waste room
10. Sink in Biology Lab
11. Floor in front of Hood in Biology Lab
12. Bench top on left side of Biology Lab
13. Floor in front of left bench
14. Bench top on right side of Biology Lab
15. Floor in front of right bench
16. Bench top in Dark Room
17. Floor in front of bench top in Dark Room

Procedure: A clean, moistened 4.25 cm Whatman filter paper is used per test. Wipes are counted for 10 minutes in the Gamma and Liquid Scintillation counters. Contaminated areas exceeding 0.0001 in Ci (2200 dpm) are cleaned and re-tested.

- D. The RSO shall inform all users of appropriate rules and regulations and changes therein included in the MilliGen Radiation Safety Manual (in preparation), written to conform to the NRC good safety practices and regulations, and see that such safety practices are enforced.
- E. The RSO will see that radiation work is done with due precautions (i.e., personnel monitoring devices are worn when in the radiation laboratory, disposable gloves are worn when handling radioactivity, no mouth pipetting is done, appropriate radiation signs and labels are used and signs prohibiting smoking, eating and drinking are evident as included in the MilliGen Radiation Safety Manual. ^{32}P experiments are done in a lucite shielded area and safety glasses are worn.
- F. Personnel will be monitored by the use of film badges supplied and analyzed at monthly intervals by R.S. Landauer Jr. and Co., 2 Science Road, Glenwood, Illinois 60425-1586; (312) 755-7000
- G. The RSO shall keep records of personnel monitoring, laboratory monitoring, incoming radiation and outgoing radioactive waste in accordance with 10 CFR parts 20 and 30, and that proper monitoring is done.
- H. The RSO will see that proper and timely calibrations are done and records kept for radiation detection instruments.

ITEM 11

Waste Management

Radiation waste shall be packaged and checked for radioactivity according to the MilliGen Radiation Safety Manual. These procedures are written to comply with the NRC regulations on disposal of radioactive waste.

- A. General Waste (^3H , ^{14}C , ^{35}S , and ^{125}I)
Removal of general waste will be by:

ADCO Services Inc.
P.O. Box 35
Tinley Park Illinois 60477
(312) 429-1660

- B. ^{32}P waste will be stored within dated steel drums (for 10 half lives at which time the material will have decayed to background and can be discarded in a normal waste container after the radioactive labels have been removed.
- C. All calibration sources will be returned to the manufacturer for proper waste disposal.

June 17, 1988

U.S. Nuclear Regulatory Commission
Attn: Glenda Jackson
License Fee Management Branch
Div. of Accounting and Finance
Office of Administration and
Resources Management
Washington, D.C. 20555

Dear Ms. Jackson:

Enclosed is a check for \$240 to complete our application fee. Please refer to CONTROL NUMBER 108918. We had previously sent a check for \$460.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Paul Reiss
mrc

Paul Reiss
Senior Scientist

Enclosure

RECEIVED
JUN 21 10:40
MILLIPORE
14-FEE MANAGEMENT

May 11, 1988

Ms. Jenny Johansen
U.S. Nuclear Regulatory Commission
Region 1
Nuclear Materials Safety Section B
631 Park Avenue
King of Prussia, PA 19406

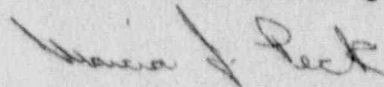
Dear Ms. Johansen:

Our check for \$460.00 was inadvertently sent on May 10, 1988 without the enclosed license application.

For your reference a copy of our check #008307 is enclosed. We are sorry if this has caused you any inconvenience.

Sincerely,

MilliGen Div. of Millipore



Marcia J. Peck
Accounting Administrator

MJP/kc

Enclosure

Send check within
5 days

REQUEST FOR PAYMENT

with attached
paperwork

Please make check payable to:

U.S. Nuclear Regulatory Commission

RECEIVED
1988 MAY 11

Amount 460.00

Charge Acct. RBG 680000

P. O. _____

3 MAY 11 1988

Reason for payment:
To obtain license for using
radioactive materials

OK'd by Chute 5/2/88

ma 5/2/88

8460

Milligen
ATTN: Mr. Paul Reiss
75 Wiggins Avenue
Bedford, MA 01730

JUN 13 1988

Gentlemen:

This refers to your recent application for a materials license.

We received your check for \$460. Your application, however, is subject to an application fee of \$700 as specified in §170.31 (3M) of 10 CFR 170, copy enclosed. Payment of the additional \$240 should be made to the U.S. Nuclear Regulatory Commission and mailed to my attention at our Washington, D.C. address.

Your application will be processed by the Region I Licensing staff located at 475 Allendale Road, King of Prussia, Pennsylvania 19406. The additional fee, however, is required prior to issuance of the license. When submitting the fee, please refer to CONTROL NUMBER 108918.

Sincerely,

Signed by:
Glenda Jackson
Glenda Jackson
License Fee Management Branch
Division of Accounting and Finance
Office of Administration and
Resources Management

Enclosure:
10 CFR 170

cc: Region I

DISTRIBUTION:
Pending Fee File
ARM/DAF R/F
LFMB R/F (2)
DW/RI/Milligen

OFFICE: ARM/LFMB *sk*
SURNAME: SKimberley:rej
DATE: 6/9/88

ARM/LFMB *sk*
GJackson
6/10/88

