NRC FORM 313
(7-86)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

030-30029

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
NUCEAR 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
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
- [X] B. AMENDMENT TO LICENSE NUMBER 20-28040-01
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Serono Laboratories, Inc.
76 Pacella Park Drive
Randolph, MA 02368

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

Same as section 2 above.

9003070162 890824
REG1 LIC30
20-28040-01 PDR

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Maureen A. McLaughlin

TELEPHONE NUMBER: (617) 963-8154X425

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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)*
FEE CATEGORY: 3M
AMOUNT ENCLOSED: $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	DATE
Maureen A. McLaughlin	Maureen A. McLaughlin	Q.C. Manager/RSO	5/12/89

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

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

c. NUMBER OF BEDS

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)*
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMD	Jun. 5	3M		

AMOUNT RECEIVED	CHECK NUMBER	DATE
$120	NRR (802 3523)	110763 6/12/89

OFFICIAL RECORD COPY ML 10

MAY 25 1989

May 12, 1989

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

Dear Sir/Madam:

I am contacting you at this time to notify you of our need to amend our byproduct material license. The license in question was issued to Serono Laboratories, Inc. on July 14, 1987 (License No. 20-28040-01, Docket No. 030-30029, Control No. 107287).

An amendment to the above license was requested in a letter dated September 19, 1988. An amendment (Amendment No. 01, Control No. 109673) was issued in November 1988. Therefore, this letter represents our second request for an amendment to our byproduct license.

I would greatly appreciate it if you could expedite the processing of this byproduct material license amendment request as our need at this time is urgent.

Please find enclosed $120.00 as payment for an amendment to a byproduct license under category 3M (10 CFR Part 170).

The amendment to Serono Laboratories existing byproduct license shall include the following which are attachments to NRC Form 313:

Section 5) RADIOACTIVE MATERIAL:

Inclusion of the following radioactive compounds in addition to the one stated (125-I) in our original application for license approval.

Element and Mass Number	Chemical and/or Physical Form	Maximum Amount Which Will Be Possessed At Any One Time
Tritium H-3 (Hydrogen -3)	Any	25 mCi
Carbon C-14	Any	25 mCi
Sulfur S-35	Any	25 mCi
Phosphorous P-32	Any	25 mCi
Unquenched Stds.		
Tritium H-3	Toluene	< 0.2 uCi
Carbon C-14	Toluene	< 0.1 uCi

The unquenched standards listed above (H-3 and C-14) are argon-purged and flame-sealed in glass ampules made from low activity borosilicate glass. These standards will be used for verification of instrument performance.

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

Items and quantities listed above will be used for research, development, laboratory analysis and storage of licensed material pursuant to the items and conditions of the license issued by the NRC.

NOTE: Licensed materials will not be used in or on human beings nor will licensed materials be used for purposes of animal research of any kind.

The above listed radioactive compounds will be utilized by the Protein Chemistry Group to perform metabolic labelling experiments and immunoassays. Each of these experiments will require the use of approximately 50 - 100 uCi of radioactive material (Refer to list in Section 5). Metabolic labelling experiments will be performed in a Baker Model BC-4, Class II, Type BZ, Biological Safety Cabinet with 100% exhaust capacity of 492 cubic feet per minute ducted to the outside. This particular laminar flow hood is being utilized as the experiments performed must be conducted under sterile conditions. These labelled oligosaccharides will be analyzed using various analytical instruments and methods. The Protein Chemistry Group may also use a Fisher Contempra Safety-Flow, Epoxy-Lined, By-Pass Fume Hood in addition to the Baker Hood listed above.

In addition, Phosphorous-32 will also be utilized by the Quality Control Group to perform Reverse Transcriptase Activity Testing. This assay is useful for the detection of retrovirus production by cultured cells. The assay quantitates the incorporation of radiolabeled nucleotides into DNA that can be bound to DEAE paper. If retrovirus is present in the test article, radiolabeled nucleotides incorporate into DNA which is copied from a viral template. If reverse transcriptase activity is not present in the test article, synthesis will not occur, and no

labeled DNA should bind to the DEAE paper. Each assay will require the use of approximately 25 uCi of radioactive material (P-32).

Laboratory personnel in both departments will utilize radiolabeled nucleotides, proteins and antigens in various analytical test methods. Such testing may include methods such as: immunoradiometric assays, hybridization assays, and a variety of radiochemical electrophoresis methods (i.e., Western blotting).

All test procedures involving the use of any radioactive compounds will be conducted by trained laboratory personnel only within restricted laboratory areas.

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

Maureen A. McLaughlin (Quality Control Manager/RSO) will continue to be responsible for the overall Radiation Safety Program.

Susan J. Monahan will act as the Radiation Safety Assistant with regards to training issues and general radiation safety activities (waste management, surveying/monitoring, maintenance of radioactive material acquisition logbook, equipment calibrations, etc.).

Please find attached her resume listing relevant past experience. Refer to attachments A-1 + A-2

Section 8) TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTTING RESTRICTED AREAS:

Individuals who will be working with radioactive materials and /or individuals who frequent "restricted" areas will undergo general radiation safety training as outlined in Serono Laboratories' original Byproduct Material License Application as well as any additional training specific to a particular test procedure as deemed necessary by the Radiation Safety Officer and Department Supervisor. Training records will be maintained by the Radiation Safety Department for each individual in question.

Section 9) FACILITIES AND EQUIPMENT:

1) Facilities:

The layout of the facility (76 Pacella Park Drive - Randolph, MA) has remained relatively the same with the following exceptions:

A) Additional offices have been added.

B) A new Quality Control Laboratory has been added. (Q.C. LAB II).

Please see attached diagram. (Attachment B)

To date use of radioactive materials has been restricted to Quality Control Lab I as stated in our original license application. We would like to amend our license to include the following "restricted area" laboratory locations:

Quality Control Lab II

Protein Purification/Protein Chemistry Lab

These "restricted areas" will be equipped with locking devices to restrict access by unauthorized personnel. In addition, activities involving the use of radioactive materials will be segregated within these "restricted" laboratory areas in order to guard against the spread of contamination within each laboratory. "Restricted areas" are designated in 'red' on the attached diagram.

We would also like to include Cold room II for additional cold storage of these licensed materials. Areas to be used for cold storage are designated in 'yellow' on the attached diagram.

Our "Radioactive Waste Storage Room" is scheduled to be relocated. This room will be located in a general warehouse area and is designated in 'blue' on the attached diagram.

II) Equipment:

The following equipment/supplies will be purchased and utilized in addition to our existing list of radiation protection/detection devices:

a) Baker Model BC-4, Class II, Type BZ, Biological Safety Cabinet with 100% exhaust capacity of 492 cfm ducted to the outside.

b) Fisher Contempra Safety-Flow, Epoxy-Lined, By-Pass Fume Hood.

c) Packard Minaxiß TRI-CARB 4000 Series Liquid Scintillation Counter.

d) Beta shielding constructed of 3/8" transparent acrylic to provide maximum protection from ß-emitting radionuclides.

e) Additional waste containers will be supplied for segregation of absorbed liquid and solid waste.

General Supplies:

g) Assorted disposable lab supplies will be used, i.e., syringes, petri dishes, 96-well microtiter plates, test tubes, etc. These materials will be disposed of as solid contaminated waste by a licensed radioactive waste disposal firm.

Section 10) RADIATION SAFETY PROGRAM:

Serono Laboratories, Inc. will continue to operate under the general rules and regulations pertaining to acquisition, handling, storage and disposal of radioactive materials as outlined in their original Byproduct Material License Application. This will also include instruction to personnel pertaining to general safety issues as well as posting of relevant documents in order to comply with Code of Federal Regulations, Title 10, Part 19 - "Notices, Instructions, and Reports to Workers; Inspections."

Section 11) WASTE MANAGEMENT:

Serono Laboratories, Inc. will retain the services of U.S. Ecology, Inc. as our licensed waste disposal firm. All radioactive waste will be disposed of in accordance with NRC/U.S. Ecology rules and regulations.

U. S. Ecology, Inc.
9200 Shelbyville Road
Suite 526
P.O. Box 7246
Louisville, Kentucky 40207
(502) 426-7160
Generator # MAR 99-002-5504

If you should require any additional information regarding this amendment request, please feel free to contact me at (617) 963-8154 extension 425 during working hours.

Thank you very much in advance for you cooperation and assistance in this matter.

Sincerely,

Maurice A. McLaughlin

Maureen A. McLaughlin
Quality Control Manager/RSO

Serono Laboratories, Inc. Attachment A - 1
Application for Amendment to License # 20-28040-01
May 12, 1989

As stated in Serono Laboratories original Application for License Approval (dated 10/85) an individual would be chosen to assist the RSO in handling routine radiation safety functions and would act as a back-up RSO in the event of the acting RSO's absence. Susan J. Monahan will act as the Assistant to the Radiation Safety Officer, in conjunction with her duties as Quality Control Scientist. She is trained and experienced in radiation protection and in the use and handling of radioactive materials.

She has been employed by Serono Laboratories, Inc. from September 1988 to present in the role of Quality Control Scientist.

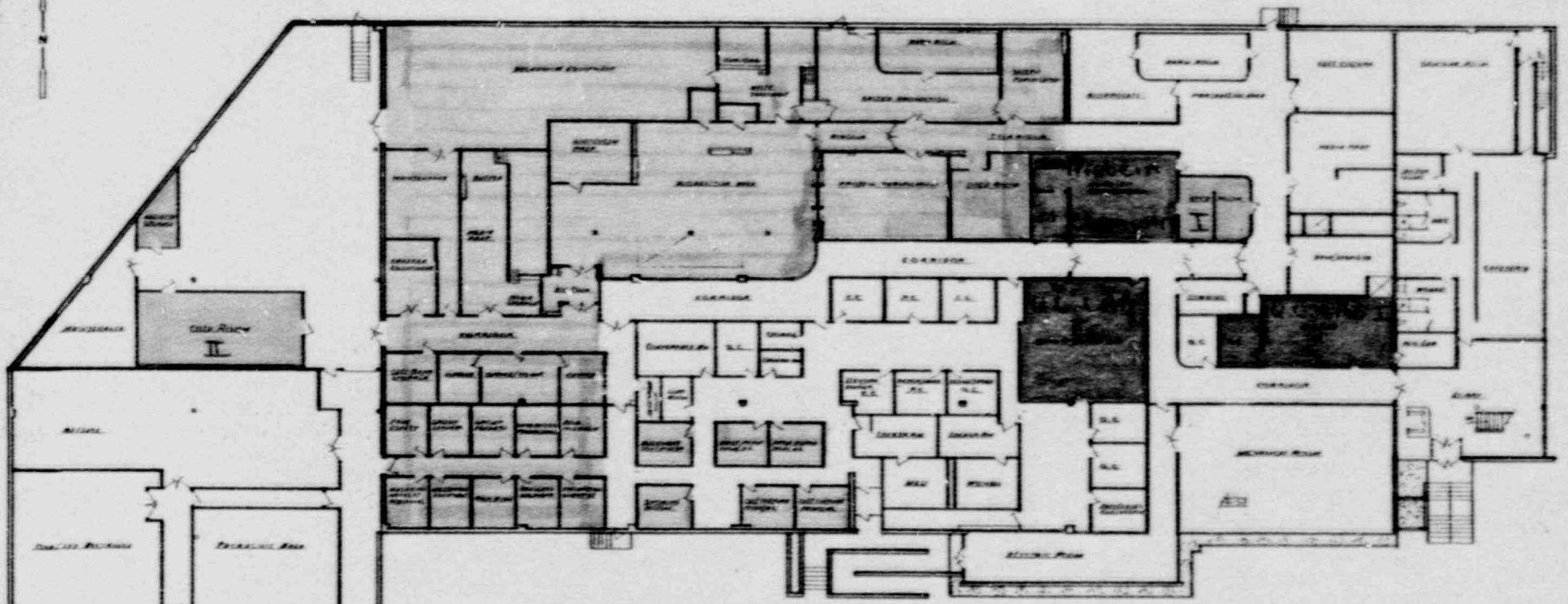
Her background/experience includes:

- Protein iodinations
- Radioimmunoassay techniques
- Receiving and handling radioactive compounds
- Radioactive decontamination procedures
- Instruction in Radiation Safety Procedures
- Storage and disposal of radioactive materials
- Research and development projects involving radioactive compounds

Attachment A-2

SUSAN J. MONAHAN
56 Goldencrest Avenue
Waltham, MA 02154

EDUCATION	Springfield College, Springfield, MA B.S. Biology, 1983
EXPERIENCE December 1985 - Present	Beth Israel Hospital, Division of Gastroenterology Boston, Massachusetts Research Technician analyzing the physiological significance of gastrointestinal peptides. Study methods include rat antral mucosal tissue culture, affinity chromatography, column characterization, radio-immunoassay, radioactive labelling of such peptides and their purification by ion-exchange and gel chromatography
May 1986 - Present	Study Coordinator (Beth Israel as a center) for a nation-wide multicenter clinical trial sponsored by a private corporation. Responsibilities include patient screening, scheduling of follow-up visits, compiling data, dispensing of study medication and instructing patients on their particular regimen.
March 1984 - November 1985	Cambridge Medical Diagnostics, Inc. Billerica, Massachusetts Production Supervisor providing supervision and instruction to laboratory technicians responsible for the manufacture of radioimmunoassay kit components. Responsible for document revision to meet governmental guidelines. Research and Development Technician involved in new product development, specifically coated tube radioimmunoassay technology. Production Technician responsible for the manufacture of radioimmunoassay kit components. Duties include the radioactive labelling of hormones as well as their purification by such methods as HPLC, TLC and Liquid Phase Column Chromatography.
VOLUNTEER December 1981	Baystate Medical Center Springfield, Massachusetts Observed technicians in microbiology and hematology laboratories.



Legend:

Restricted Areas - Red
Cold Storage - Yellow
Rad. Waste Storage - blue
New construction - green
(June 1989 - early 1990)

SERONO-RANDOLPH
76 Pacella Park Drive
Randolph, MA 02368

FIRST FLOOR PLAN

OFFICIAL RECORD COPY ML 10 MAY 25 1989

110763

Attachment 6

MJ-1D
5-30-89

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: ---
EXP. DATE: 19920731
FEE COMMENTS: ---

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: SERONO LABORATORIES, INC.
RECEIVED DATE: 890525
DOCKET NO: 3030029
CONTROL NO.: 110763
LICENSE NO.: 20-28040-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $120.00
CHECK NO.: 96674 - INVOICE # NUMBER
NO CHECK NUMBER

3. COMMENTS

SIGNED BMW
DATE 5-30-89

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /✓/)

1. FEE CATEGORY AND AMOUNT: 3M $120

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL ---
LICENSE ---

3. OTHER ---

SIGNED S. Kingsley
DATE 6/12/89