

APPENDIX A - NRC Form 313

NRC FORM 313 (1-84) 10 CFR 30, 32, 33, 34, 35 and 40 U.S. NUCLEAR REGULATORY COMMISSION APPROVED BY OMB 3150-0120 Expires 5-31-87

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 19396

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  
 780 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 \_\_\_\_\_  
 C. RENEWAL OF LICENSE NUMBER \_\_\_\_\_

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)  
 Biogen, Inc.  
 14 Cambridge Center  
 Cambridge, MA 02142

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED  
 14 Cambridge Center  
 Cambridge, MA 02142

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION  
 Dr. William S. Kelley

TELEPHONE NUMBER  
 (617)864-8900

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)  
 FEE CATEGORY AMOUNT ENCLOSED \$230.00

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: *William S. Kelley*  
 TYPED/PRINTED NAME: William S. Kelley  
 TITLE: Vice President for Production & Proc. Dev.  
 DATE: 2/17/89

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS		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)	
<\$250K	\$1M-3.5M				YES <input type="checkbox"/> NO <input type="checkbox"/>
\$250K-500K	\$3.5M-7M				
\$500K-750K	\$7M-10M				
\$750K-1M	>\$10M				

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
App	Mar-7-89	3E		M. Pusey
AMOUNT RECEIVED	CHECK NUMBER			DATE
\$230	000782			3/5/89

PRIVACY ACT STATEMENT ON THE REVERSE

9002090066 890428  
 REG1 LIC30  
 20-19808-02 PDR

10.9-19

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Introduction

Biogen Research Corp. currently possesses byproduct material license no. 20-19808-01. We are requesting an additional license to possess and use a self-shielded gamma irradiator for biological studies.

We would like to also report that we have hired a health physics consultant, Victor Evdokimoff to assist us with our radiation safety program. Mr. Evdokimoff, a certified health physicist, is the Director of Radiation Protection at Boston University Medical Center. He has over 20 years experience as an industrial health physicist, as well as current responsibility for a broad medical license program that includes a gamma cell irradiator.

Item 5. Radioactive Material to be Possessed

The irradiator contains Cesium 137 at a nominal activity of 1400 Curies per source, from Atomic Energy of Canada Limited. The Gamma Cell 1000 consists of 2 sources (model B) with a total maximum possession limit at any one time of 2800 curies.

Safety information on this particular model has been registered with USNRC.

Item 6. Purpose For Which Licensed Material will be Used

To irradiate blood and blood components as well as other biological samples.

Item 7. Individual Responsible for Irradiator Radiation  
Safety

Dr. David Thomas has training in radiation protection plus extensive experience with radioisotopes including a gamma cell irradiator. He will be responsible for this machine. His credentials are included in form 313m.

### Item 8. Training

- 1) The training program will cover the following topics:
  - a) The NRC Biogen irradiator license
  - b) Workers rights and responsibilities
  - c) Radiation Physics
  - d) Biological effects of radiation
  - e) Design and exposure potential of the Cs-137 irradiator
  - f) Principles of exposure control to irradiator operators
    - i. time, distance, shielding
    - ii. wearing personnel monitors
    - iii. using radiation detection equipment
  - g) How to use the irradiator
  - h) Question and answer period

This training is usually several hours long.

2) As a means of evaluating individuals who have completed the training program, a written multiple choice examination covering all aspects of the training program will be administered. Each individual must achieve a score of 70 percent to be allowed to use the irradiator. Each individual's test will be maintained as a record to document training.

3) Training will be performed by any of several individuals who are qualified in radiation safety. These individuals are Dr. Thomas and the Radiation Protection Office. In addition, we have the services of our health physics consultant, Victor Evdokimoff, who has 20 years experience in health physics including training and use of gamma cell irradiators.

4) Irradiator on-the-job training will be given to trainees under close supervision of Dr. David Thomas. This will consist of a minimum of several complete irradiation procedures. This will enable the trainer to evaluate trainee understanding of the various switches, indicator lights, timer procedures, including any emergency of the irradiator machine.

110344

Item 9. Facilities and Equipment

The irradiator is located on the ground floor of Biogen Inc. where exposure potential to personnel will be minimized.

This room is indicated on the attached floorplan.

To provide security, the irradiator room will be locked when unattended to prevent access by unauthorized persons. To assure fire protection in this room, there is a sprinkler system. The room also has a low fire potential.

Item 10. Radiation Safety Program

10.1 Personnel Monitoring Equipment

All personnel who use the irradiator will be required to wear whole body film badges to assess radiation exposure doses in accordance with the requirements of 10CFR20.202. These badges are supplied by R.S. Landauer Jr. and have been accredited by NULAP of the National Bureau of Standards. These badges are changed monthly.

10.2 Radiation Detection Equipment

The facility has available numerous calibrated, operable survey meters that can measure exposure rates to 200 milliroentgen per hour.

The instrument will be calibrated so that readings are within  $\pm 20\%$  of the exposure rate for Cs-137 over the range of the instrument. They will be calibrated annually, checked quarterly and after servicing. Calibration records will be kept for a minimum of 2 years after each calibration. The geiger counter will be calibrated within the conditions of our byproduct material license no. 20-19808-01. We also could calibrate this meter with other options such as:

1) Returned to Ludlum Measurements Inc., Sweetwater, Texas.

or

2) Neil Gaeta CHP  
35 Grove St.  
Medford, Ma. 02155  
NRC license no. 20-20743-01



### 10.3 Leak Testing

Leak testing of the sealed sources in the irradiator will be performed every six months. The measurement of the leak-test sample must be analyzed on an appropriate instrument to detect 0.005 microcuries of Cesium 137 removable contamination. Any source leakage at .005 microcuries or above will be reported promptly to Dr. Thomas and Radiation Protection. The irradiator will be removed from use and the source(s) shall be repaired in accordance with USNRC requirements. Leak testing will be performed by individuals listed under the following 2 options:

a) Under the conditions specified for our byproduct material license 20-19808-01 for leak testing performed by or under the supervision of the Radiation Safety Officer

or

b) Performed and analyzed by Victor Evdokimoff DHP

Boston University Medical Center

20-02215-01

#### 10.4 Operating and Emergency Procedures

All personnel using the irradiator will be provided with written operating and emergency procedures. These will be maintained in the irradiator room. A written log also in this room will document who used the machine, date of use and other pertinent information. The emergency procedures will be conspicuously posted in the area. The following topics will be covered in these procedures and will be available prior to use of the irradiator.

- a) Step-by-step procedures for operation of the irradiator.
- b) Determination and recording of radiation doses to persons operating the irradiator.
- c) Methods to ensure that only authorized persons will use the irradiator.
- d) Inspections, test procedures and maintenance to ensure that all safety interlocks, devices and components associated with the irradiator are functioning properly. It is prohibited to modify the irradiator, for example, changing the safety control system or removing the source. This could be life-threatening.
- e) Emergency situations will require vacating the irradiator room if a source should hang up, locking the door and notifying the person responsible for the irradiator (Dr. Thomas). These situations can be assessed by GM exposure reading. Emergency off-hour telephone numbers such as Dr. Thomas', the RPO, the NRC and AECL will be conspicuously posted.

110344

#### 10.5 Plans for Installation and Certain Repairs

Irradiator installation, pre-operational checks and repairs or alterations involving removal of shielding or access to the licensed material will be performed by an AEOL trained representative.

## Item 11. Waste

### 11.1 Disposal

The Cesium 137 sealed sources, should they need to be disposed as radioactive waste, will be transferred only to the original supplier of the irradiator source, or a commercial firm licensed by the USNRC or an Agreement State to accept this radioactive waste.

### 11.2 Transportation

Should this irradiator need to be transported to another location, we will seek guidance from the USNRC on the proper packaging and other pertinent regulations.

EXHIBIT 2  
SUPPLEMENT A

SUPPLEMENT U.S. NUCLEAR REGULATORY COMMISSION  
**TRAINING AND EXPERIENCE  
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER  David Thomas	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
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3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
N/A		

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY (formal course)	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	NIH 1975 Washington Univ. 1979/80 Univ. of Michigan 1985	16 8 4	24 24 24
b. RADIATION PROTECTION	Same as above	Same	Same
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Same as above	Same	Same
d. RADIATION BIOLOGY	Same as above	Same	Same
e. RADIOPHARMACEUTICAL CHEMISTRY	Same as above	Same	Same

**5. EXPERIENCE WITH RADIATION. (Actual Use of Radioisotopes or Equivalent Experience)**

ISOTOPE	MG USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
<sup>3</sup> H	10	Univ. of Colorado	5000	biosynthetic labelling
"	10	NIH	5000	
<sup>14</sup> C	5	NIH	500	
<sup>35</sup> S	10	NIH	500	
<sup>125</sup> I	10	Washington Univ.	5000	Labeling of cells and proteins
<sup>51</sup> Cr	5	Washington Univ.	2000	
<sup>32</sup> P	10	Univ. of Michigan	100	labeling of cells
<sup>3</sup> H	10	Univ. of Michigan	5000	"
<sup>14</sup> C	5	Univ. of Michigan	1000	"
<sup>35</sup> S	10	Univ. of Michigan	2000	"
Gammacell Irradiator		Univ. of Michigan	100	irradiation of cells and mice

110344

RCS 101A, 204

**STATEMENT OF TRAINING AND EXPERIENCE**

1. Soc. Sec. No. 640-50-8774 Birthdate 5/24/47 Name David W. Thomas

2. Type of Training (Check "Yes" or "No" in Columns I and II. If "Yes" is indicated in either column, complete Columns III and IV).

	I		II		III	IV
	Formal Course		On the Job		Where Trained	Duration of Training
	YES	NO	YES	NO		
(a) Principles and Practices of Radiation Protection	X		X		NIH	2 years
(b) Radioactivity measurement monitoring techniques, and instruments	X		X		Washington Univ.	4.5 years
(c) Mathematics and calculations basic to the use and measurement of radioactivity	X		X		Univ. of MI	7 years
	X		X			

3. Formal Courses (If you checked "yes" in Column I for any of the items above, complete this item, listing all courses pertaining to the use of radiation or radioactive materials, atomic and nuclear structure, radiochemistry, radiation biology, nuclear engineering, etc.)

Title of Course	Where Trained	Duration or Date Completed	Course Content
Radiation Control — Radiation Safety Orientation Course	University of Michigan	11/85	Required by 10 CFR 19
Radiation Users Course	NIH	1975	Practical and theoretical aspects of radioactivity
Radiation Safety Course	Washington University	1979, 1980	Updated regulations for safety and handling
Training for Commercial Products	U. of M.	1984	Safety and use of

4. Experience (List actual use of radioactive materials, details of formal laboratory courses, or on-the-job training)

Nuclide	Maximum Amount (mCi)	Where Experience Was Gained	Duration	Type of Use
<sup>3</sup> H	10	Univ. of Colorado Medical School	> 5000 2 years	biosynthetic labeling of
<sup>14</sup> C	5	NIH	> 5000 2 years	cells in tissue culture
<sup>35</sup> S	10	"	500	"
<sup>125</sup> I	10	Washington University	> 5000 4.5 years	labeling of cells and prote
<sup>81</sup> Br	5	"	2000	labeling of cells
<sup>32</sup> P	10	Univ. of Michigan	7 100 2 years	labeling of cells
<sup>3H</sup>	10	"	> 5000	
<sup>14C</sup>	5	"	2000	
<sup>35S</sup>	10	"		

Signature of person in item #1  
*David W. Thomas*

5. Name of Authorized User (As specified on User's "Application for Authorization to Use Radioactive Material" — RCS 101 (Please Print))  
David W. Thomas

100  
 inoculation of cells and in vivo

BIOGEN

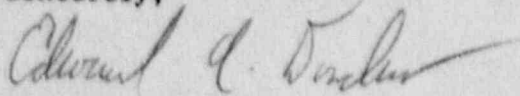
February 17, 1989

John Glenn, Ph. D.  
Chief, Section A, Region I  
U.S. Nuclear Regulatory Commission  
475 Allendale Road  
King of Prussia, PA 19406

Dear Dr. Glenn:

Attached you will find portion of our first floor existing drawing depicting the location of the room in which the Gammacell 1000 blood irradiator will be located. The floor in that room is 6" poured concrete on grade which will certainly satisfy the floor loading of 625 lbs/sq. ft. of the irradiator. The wall construction is of 10" concrete block floor to ceiling. We are installing a suspended ceiling of standard acoustical tile laid into metal track. In addition we are also installing two sprinkler heads and a smoke detector for this room. The door has a one hour fire rating and it opens into a hallway. If you require any further details, please contact me at (617) 864-8900 extension 274.

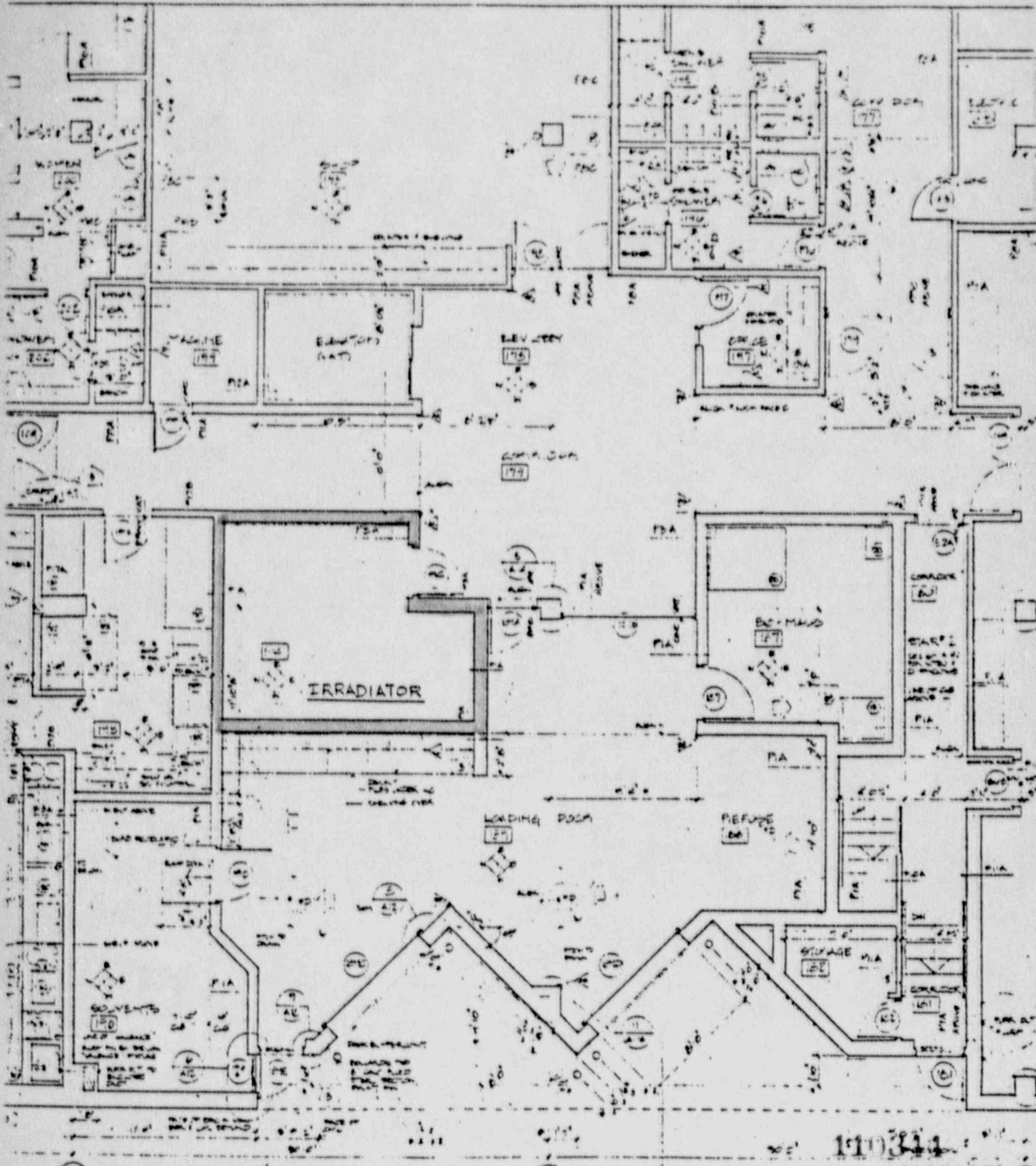
Sincerely,



Edward A. Dondero  
Project Manager

Attachment

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APB  
MS-10  
89-03-01

(FOR LFMS USE)  
INFORMATION FROM LTS  
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BETWEEN:  
LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

PROGRAM CODE: -----  
STATUS CODE: 3  
FEE CATEGORY: -----  
EXP. DATE: 0  
FEE COMMENTS: -----  
.....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED  
APPLICANT/LICENSEE: BIOGEN, INC.  
RECEIVED DATE: 890227  
DOCKET NO: 3031034  
CONTROL NO.: 110344  
LICENSE NO.:  
ACTION TYPE: NEW LICENSE

2. FEE ATTACHED  
AMOUNT: \$230.00  
CHECK NO.: 000782

3. COMMENTS

SIGNED R. J. Brown  
DATE 89-03-01

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1-75)

1. FEE CATEGORY AND AMOUNT: 3E (\$230)

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

3. OTHER -----

SIGNED Mr. Muzzoni  
DATE 3/8/89