

## 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, 36, 39, 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.

**OFFICIAL RECORD COPY**

## Licensee

In accordance with the letter dated  
September 20, 19963. License Number 06-28473-01 is amended in  
its entirety to read as follows:

4. Expiration Date June 30, 2005

5. Docket or  
Reference No. 030-314746. Byproduct, Source, and/or  
Special Nuclear Material7. Chemical and/or Physical  
Form8. Maximum Amount that Licensee  
May Possess at Any One Time  
Under This License

A. Hydrogen 3  
B. Carbon 14  
C. Phosphorus 32  
D. Sulfur 35  
E. Chlorine 36  
F. Iodine 125

A. Any  
B. Any  
C. Any  
D. Any  
E. Any  
F. Any

A. 120 millicuries  
B. 20 millicuries  
C. 50 millicuries  
D. 25 millicuries  
E. 1 millicuries  
F. 30 millicuries

## 9. Authorized use

A. through F. Research and development as defined in 10 CFR 30.4.

## CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 35 Northeast Industrial Road, Branford, Connecticut, and 15 Northeast Industrial Road, Branford, Connecticut.
11. Licensed material shall be used by, or under the supervision of John F. Tallman, Ph.D., Ram (T.V.) Ramabhadran, Ph.D., or Dorothy W. Gallager, Ph.D.
12. The Radiation Safety Officer for this license is Ram (T.V.) Ramabhadran, Ph.D.
13. Licensed material shall not be used in or on human beings.
14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
15. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 90 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

9610210119 961010  
PDR ADOCK 03031474  
C PDR

**ML 10**

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

06-28473-01

Docket or Reference Number

030-31474

Amendment No. 02

- B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated January 2, 1990
  - B. Letter dated February 28, 1990
  - C. Letter dated April 11, 1990
  - D. Letter dated March 1, 1995
  - E. Letter dated May 24, 1995
  - F. Letter dated September 20, 1996
  - G. Letter dated October 3, 1996

Date OCT 10 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Elizabeth Ullrich

By

Nuclear Materials Safety Branch  
Region I

King of Prussia, Pennsylvania 19406

OCT 10 1996

Ram Ramabhadran, Ph.D.  
Radiation Safety Officer  
Neurogen Corporation  
35 Northeast Industrial Road  
Branford, CT 06405

Dear Dr. Ramabhadran:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. The new expiration date is stated in Item 4 of the license.

Please also note that Dr. Lodhi was not questioning why you were not included as an authorized user earlier, but because you had stated that Dr. John Tallman's absence necessitated the addition of other authorized users, Dr. Lodhi was only providing you with the information that the Radiation Safety Officer with your qualifications could also have been included as an authorized user on the license when it was renewed. Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:  
Elizabeth Ullrich



John D. Kinneman, Chief  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety

License No. 06-28473-01  
Docket No. 030-31474  
Control No. 123718

Enclosure:  
Amendment No. 02

DOCUMENT NAME: R:\WPS\MLTR\L0628473.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	SLodhi		JKinneman				
DATE	10/07/96		10/7/96		10/ /96		10/ /96

OFFICIAL RECORD COPY

**ML 10**



**Neurogen Corporation**

MS 16

Q-2

35 Northeast Industrial Road

Branford, Connecticut 06405

Telephone 203 488-8201

Fax 203 481-8683

October 3, 1996

Mr. Sattar Lodhi  
US Nuclear Regulatory Commission  
475 Allendale Rd.  
King of Prussia, PA 19400

Re: **Mail Control #123718**  
Amendment of Neurogen Corporation's NRC License #06-28473-01

Dear Mr. Lodhi:

I am writing to clarify the three issues you raised during our phone conversation last week relating to the amendment of Neurogen's NRC license.

1. Transportation of waste drums from the new facility to the current facility

As shown in Exhibit A, submitted with the renewal application, the current facility at 35 NE Industrial Road and the new facility at 15 NE Industrial Road are back-to-back and will be connected through a driveway. Vehicles carrying the waste barrels will use this route. Thus, they will always be on Neurogen property and will not be entering any public roads.

2. Addition of other supervisory personnel

You wanted to know why as the RSO I was not included in the supervisory list. Historically, when Neurogen received its first license in 1989-1990, I (as well as Dr. Dorothy Gallager) was not employed at Neurogen. Although the license was amended in 1995, we did not appreciate the need for adding other supervisory personnel at that time. The addition of new facilities and the increase in Dr. Tallman's travel schedule have made the inclusion of other supervisory personnel essential and desirable. Thus, while amending the license for addition of the new facility, we also requested the inclusion of two new supervisors.

3. Dr. Gallager's experience in use of radioisotopes:

A description of Dr. Gallager's qualification is attached.

Please call me at 203-488-8201-X3022 if you need any further clarification.

Sincerely,

Ram Ramabhadran  
Radiation Safety Officer and  
Director, Molecular Biology

OFFICIAL RECORD COPY

**ML 10**

123718

OCT - 4 1996

Dr. Dorothy W. Gallagher has been a member of the Neurogen staff since June, 1990. She is Vice President and Director of Pharmacology, overseeing research utilizing low level radioisotopes including  $^3\text{H}$ ,  $^{35}\text{S}$ , and  $^{125}\text{I}$ . This includes characterizing the interactions of novel compounds with receptors and intracellular processes using in vitro receptor binding and autoradiographic techniques on recombinant receptors, human and experimental animal tissues.

Prior to Dr. Gallagher's employment at Neurogen, she was an Associate Professor in the Yale University School of Medicine in charge of a laboratory carrying out electrophysiological, biomedical and neuropharmacological research using  $^{32}\text{P}$ ,  $^3\text{H}$ ,  $^{14}\text{C}$  and  $^{35}\text{S}$  from 1980 to 1990. From 1976 to 1980, Dr. Gallagher was a staff scientist at the National Institute of Health and licensee of the principle investigator's radioisotopic users course at the NIH.

Dr. Gallagher's research has involved supervising personnel in the regulated use and handling of low level radioisotopes for the past twenty years.

MNSB TELEPHONE CONVERSATION RECORD

Person Called: Ram Ramabhadran, RSO                      Phone No.: (203) 488 8201  
Person Calling: Sattar Lodhi                              Date: 9/27/96  
Facility Name: Neurogen Corporation                      Time: 9:45 a.m.  
                    Branford, CT  
License No.                      06-28473-01                      Docket No.    030-31474

---

Subject: Request for Additional Information

---

Summary: I called Dr. Ramabhadran to request the following:

- (1) Radioisotopes that the proposed user (Dr. Gallagher) has used in the past;
- (2) Will the transfer of waste drum between the two locations be via public roads; and if so they must be transported in accordance with DOT regulations.

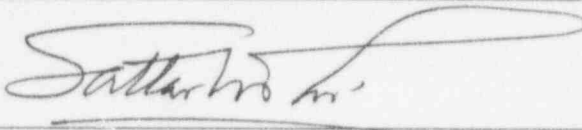
He was not available and I left a message for him to call back

9/27/96, 10:35 a.m. RSO returned my call. He promised that he will send the list of isotopes that Dr. Gallagher has previously used, and he confirmed that the transportation of waste drums between the two facilities will not be on public roads, but will be from the backside of the buildings using trollies like golf carts to haul the drums.

---

Action Required/Taken: Document/wait for response

---

Signature: 

Mail Control No. 123718

---

OFFICIAL RECORD COPY

**ML 10**



**Neurogen Corporation**

030-31474

35 Northeast Industrial Road  
Branford, Connecticut 06405  
Telephone 203 488-8201  
Fax 203 481-8683

September 20, 1996

Mr. Frank Costello  
Section Chief, Nuclear Material Safety  
US Nuclear Regulatory Commission  
475 Allendale Rd.  
King of Prussia, PA 19400

Re: Amendment of Neurogen Corporation's NRC License #06-28473-01

Dear Mr. Costello:

I am seeking an amendment of Neurogen Corporation's NRC license due to expire June 30, 2000. The main purpose of the amendment is to include a new facility under construction as an area of radioisotope use under the current license. The new facility is being constructed to accommodate the growth and expansion of Neurogen. We are hoping to move into the new facility in January 1997 by relocating several user groups in the current building to the new laboratories.

Concomitantly, I am also requesting the addition of two other members of the Neurogen senior staff as supervisors on the license along with John Tallman. This addition is to accommodate John Tallman's absences due to job related travel.

No amendments to the type and quantity of isotopes, or the nature of their use, is requested.

Location of the new facility: The new facility under construction is a part of a building located behind the current facility. Exhibit A indicates the location of new site in relation to the current site at 35 Northeast Industrial Rd. The street address of the new facility is 15 Northeast Industrial Road.

**Please note that all isotope deliveries will continue to be received at the current facility, 35 Northeast Industrial Road.** The two facilities are contiguous and will be linked by a walkway that will permit the safe transfer of materials and equipment between the two facilities. All wastes generated at the new facility will be brought back to the current facilities for in-house decay or for shipment to the broker. Large waste containers will be moved between the facilities with the aid of mechanical devices and transferred in motorized vehicles. Source materials and experimental samples will be hand-carried between the two facilities in sealed containers. An outer container will be used to transport the sealed, source-container.

OFFICIAL RECORD COPY

ML 10

123718

SEP 23 1996

We have recently added a large waste storage room to the current facility sufficient to handle wastes from both facilities. This storage room, shown in Exhibit A, is 1000 square feet. The access to this room is restricted and is controlled by a security card reader. Active waste collection containers, as well as those waiting for pick up by the broker or for in-house decay, are maintained in this room along with the inventories. The room is equipped with a sink for cleanup if needed. The room is surveyed periodically.

Description of the new facility: Exhibit B shows the layout of the new laboratories. This facility is a typical research facility much like the current facilities. The areas designated for the use of radioactive material are highlighted. The research carried out at the new labs will be similar to that conducted at the present facilities. Also shown are two interim waste storage rooms for coordinating and consolidating wastes before transfer to the large storage room in the current facility (see Exhibit A).

Storage and handling of radioactive material, and monitoring of both buildings and personnel, will be exactly as described in the current license. All policies and procedures in force in the current facility will be extended to the other facility. Both buildings will be under the supervision of RSO, Ram Ramabhadran.


Addition of supervisory personnel: Following up on the suggestion from your office, I request the addition of two supervisory personnel to the license. According to the terms of the current license, John F. Tallman is designated as the sole individual supervising the use of the licensed material. Because of Neurogen's growth and the concomitant absences of Dr. Tallman due to travel, I request the addition of the following individuals as supervisors:

Ram (T.V.) Ramabhadran, Ph.D., Director, Molecular Biology, and RSO  
Dr. Dorothy W. Gallagher, Ph.D., VP Pharmacology

Dr. Ramabhadran was added as the RSO in the recent amendment. His qualifications have been submitted previously. Dr. Gallagher has over twenty-five years of experience in the use of radioisotopes in pharmacology research. She has worked at several academic institutions including Yale University Medical School. Currently Dr. Gallagher directs the pharmacology group of Neurogen.

A check for \$610 towards the amendment fee is attached. Please, contact me at 203-488-8201 (phone) or 203-481-8683 (FAX) if you have any questions or need further information.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Ram Ramabhadran', with a long horizontal flourish extending to the right.

Ram Ramabhadran  
Radiation Safety Officer and  
Director, Molecular Biology

Exhibit A

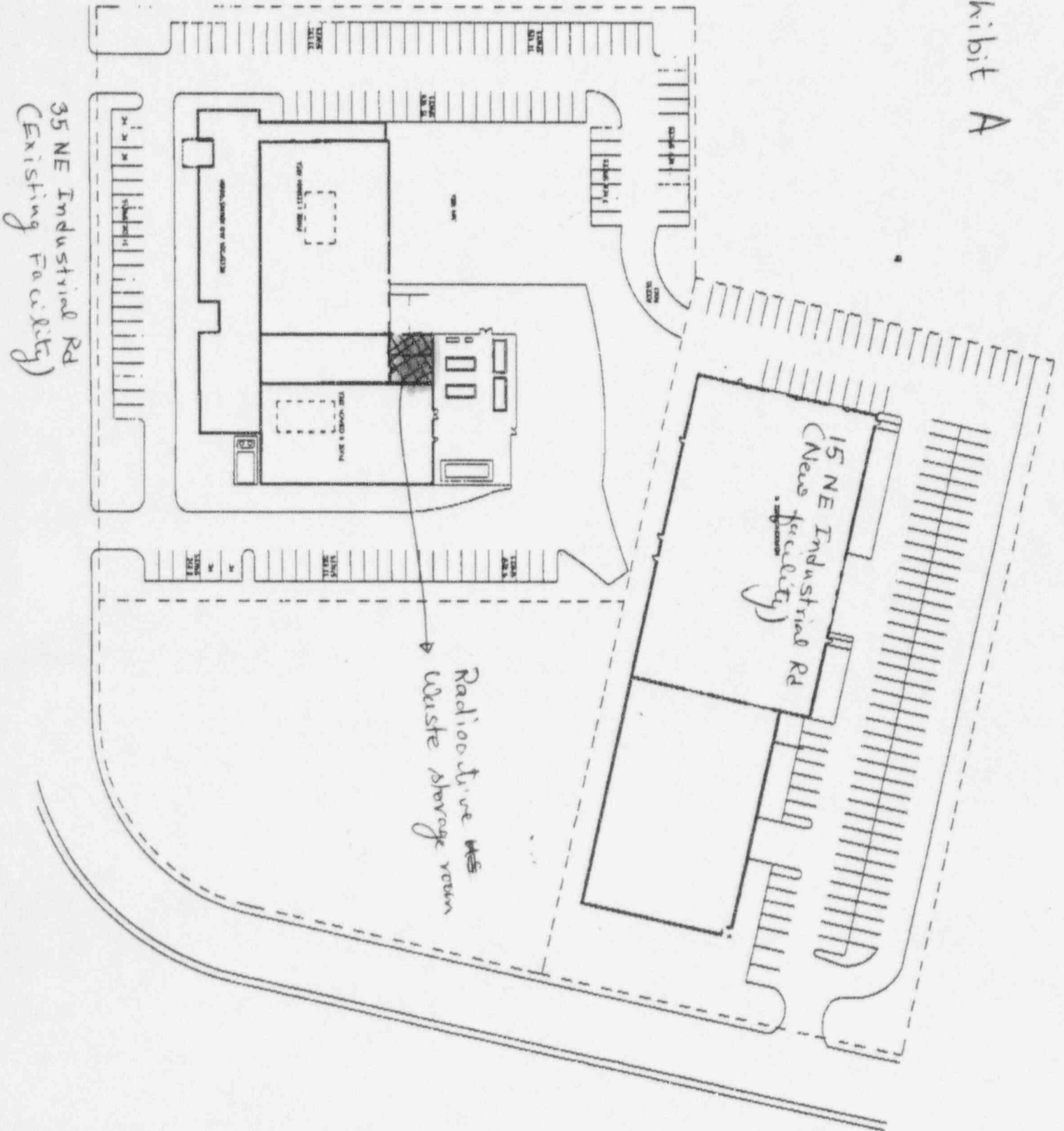
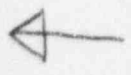
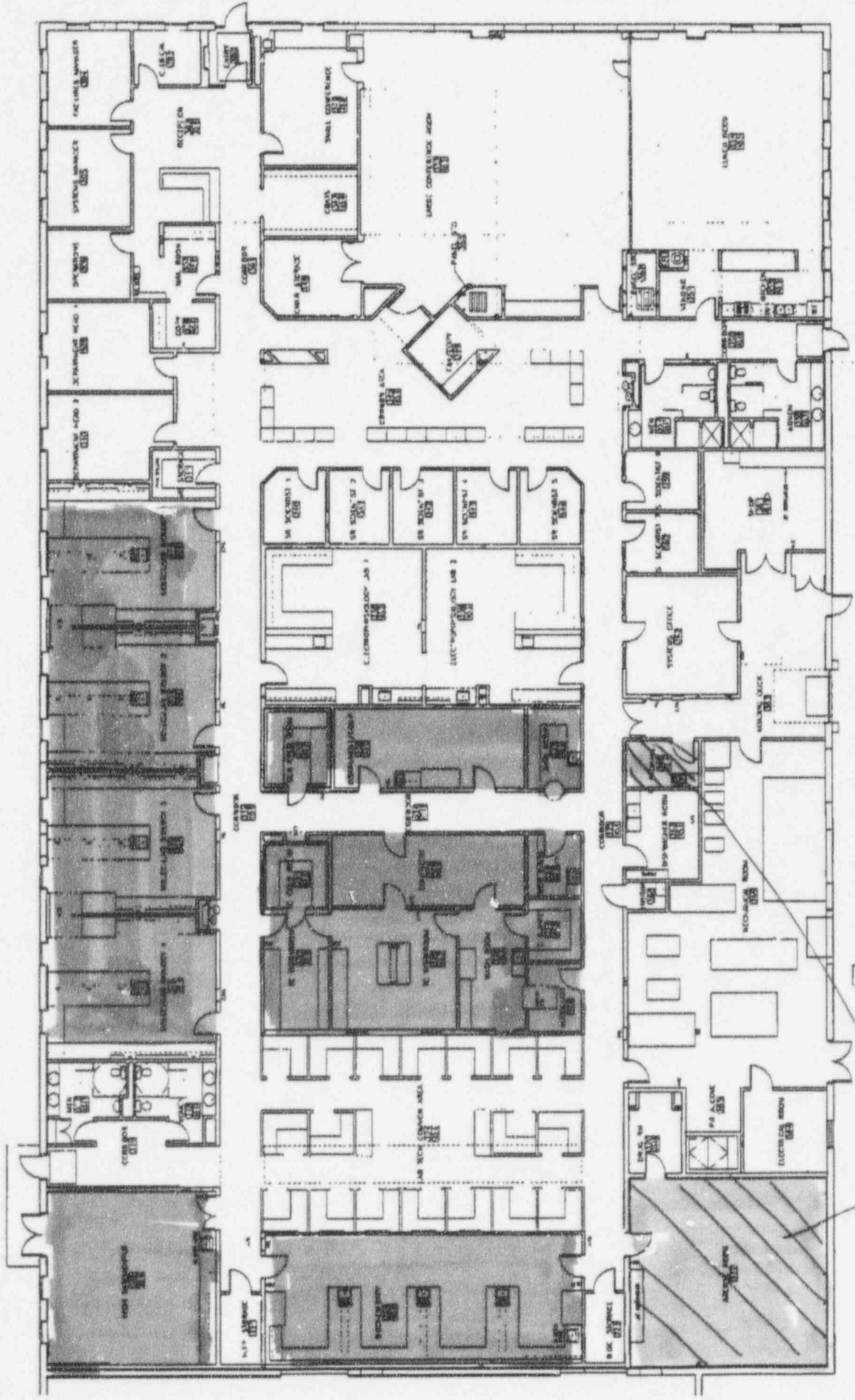


Exhibit B

35 NE Industrial Rd  
(Current Facility)



Labs where  
isotopes may be  
used.



Temporary Waste Storage Room

(FOR LFMS USE)  
INFORMATION FROM LTS

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

```
: PROGRAM CODE: 03620  
: STATUS CODE: 0  
: FEE CATEGORY: 3M  
: EXP. DATE: 20050630  
: FEE COMMENTS:  
: DECOM FIN ASSUR REQD: N
```

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: NEUROGEN CORPORATION  
RECEIVED DATE: 960923  
DOCKET NO: 3031474  
CONTROL NO.: 123718  
LICENSE NO.: 06-28473-01  
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: \$ 610.00  
CHECK NO.: 20584

### 3. COMMENTS

SIGNED  
DATE

M. A. Perkins  
9/23/98

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

1. FEE CATEGORY AND AMOUNT:

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT  
RENEWAL  
LICENSE

3. OTHER

SIGNED  
DATE

Log Rept 1  
 Remitter \_\_\_\_\_  
 Check No. 20584  
 Amount \$610  
 Fee Category 3M  
 Type of Fee AMD  
 Date Check Recd 10/2/96  
 Date Completed \_\_\_\_\_  
BA