

030-33799

VOID SHEET

TO: License Fee Management Branch  
FROM: RI  
SUBJECT: VOIDED APPLICATION

*Jul 14 3 05 PM  
121325*

Control Number: 121325  
Applicant: LEXIN Pharmaceutical Corporation  
Date Voided: 8/3/95  
Reason for Void: Licensee in letter dated 7-5-95 withdrew  
their request for an NRC material license.  
Before review. 030-33799

Rebecca J. Brown  
Signature

8/3/95  
Date

Attachment:  
Official Record Copy of  
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

Refund Authorized and processed

-No Refund Due

Fee Exempt or Fee Not Required

160005

Comments: After review

Log completed

Processed by: BA

9610160233 950603  
PDR ADOCK 03033799  
C PDR

OFFICIAL RECORD COPY ML 10



030-33749

July 5, 1995

Licensing Assistant Section  
Nuclear Materials Safety Branch  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

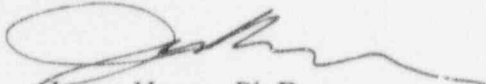
Mail Control Number 121325

Gentlemen:

This is to inform you that we are withdrawing our request for an NRC material license that was assigned your mail control number 121325. We are also requesting any refund of our application fee that we may be entitled to receive.

If you require any additional information in support of this request, please contact James Huang at 215-442-1700 ext. 212.

Sincerely,



James Huang, Ph.D.

cc: J. Fenno  
J. Hook

OFFICIAL RECORD COPY ML 10

121325

JUL - 7 1995

**L**EXIN  
PHARMACEUTICAL CORPORATION

L & L 30209

030-33799

03620

licensee  
sent a blank  
313.

February 10, 1995

Licensing Assistant Section  
Nuclear Materials Safety Branch  
U.S. Nuclear Regulatory Commission  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406-1415

Gentlemen:

Enclosed are two (2) copies of our completed Application for Materials License NRC Form 313. Also enclosed is our check in the amount of \$1,400.00 for the license fee.

If you require any additional information in support of this request please contact James Huang at (215) 442-1700 Ext.#212.

Sincerely,



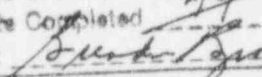
James Fenno  
Vice President

JF/thw

Enclosure: Application  
Check

cc: James Huang

I (95)

Log	Feb 10
Remitter	
Check No.	001219
Amount	\$1400
Fee Category	300
Type of Fee	APP
Date Check Rec'd	2/13/95
Date Completed	
By:	

121325

FEB 13 1995

Lexin Pharmaceutical Corporation  
Rock Plaza III, 111 Rock Road  
Horsham, PA 19044-2310

Form NRC 313( 6/93)      Application for Materials license

Item 1.  
New License application

Item 2.  
Corporate Mailing Address  
Lexin Pharmaceutical Corporation  
Rock Plaza III, 111 Rock Road  
Horsham, PA 19044-2310

Item 3  
Address where RAM used.  
  
Same as above

Item 4.  
Contact person for this application-  
  
James J. Huang, Ph. D      Phone# 215 -442-1700 Ext. 212

Item 5			
a. Element & Mass No.	b. Chemical and/or physical form	c. Maximum amount to be possessed at any one time	
A. Hydrogen 3	any	20 millicuries	
B. Carbon 14	any	10 millicuries	
C. Phosphorus 32	any	20 millicuries	
D. Phosphorus 33	any	15 millicuries	
E. Sulfur 35	any	25 millicuries	
F. Iodine 125	any except Na I	5 millicuries	

Item 6  
Purpose for which Radioactive material will be used.

Materials will be used for in vitro studies for research and development as defined in Section 30.4 (q) of 10 CFR Part 30. Iodinations will not be performed.

Item 7.  
Name of RSO and any person who will be authorized to use the material without supervision. Provide training and experience.

a) Radiation Safety Officer:  
James J. Huang, Ph. D.

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Horsham, PA 19044-2310

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b) Authorized users:	Radio nuclide use requested
James J. Huang, Ph.D.	All radio nuclides
Howard Sands, Ph.D.	All radio nuclides
Stephen D. Burrows, M. S.	All radio nuclides
Christopher P. Phillips, M. S.	All radio nuclides
Jennifer Gold Thallmayer, Ph.D.	All radio nuclides
Arthur Berger Jr. B. A.	All radio nuclides

c) The training and experience with radiation of the above are given in Appendix A.

d) Duties of the Radiation Safety Officer:

The following RSO Delegation of authority letter will be issued.

To: All Employees  
From: Chief Executive Officer  
Subject: Delegation of Authority

Dr. James J. Huang has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program ; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

Item 8

Training Program

We will establish and implement the model training program that was published in Appendix A to the Regulatory Guide 10.8 Revision 2, and including Appendix X ( Revised June 1992 ) which incorporates changes to include 10 CFR 20.1001 -20.2402. Radiation workers and ancillary staff will be trained prior to beginning work which brings them in contact with radio nuclides or with areas where radio nuclides are used or stored. Personnel will also be retrained annually or if there is a significant change in their duties as related to the use of radio nuclides. The training method will be either lectures, slide or video presentations or demonstrations. Records of training will be kept.

Item 9

Facilities and Equipment

The facilities consist of modern labs with durable easily cleaned floor and work surfaces and with proper ventilation. Chemical fume hoods are available. Shielding materials of Plexiglas, glass, metal and lead are available as are shielded storage containers. The standard assortment of incubators,

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centrifuges, drying ovens, electrophoresis equipment, etc. used in a modern laboratory are also available.

See the attached annotated drawing of the facility that identifies the areas where materials will be used and stored. Appendix B,

Item 10

RADIATION PROTECTION PROGRAM

a) We shall develop, document and implement a radiation protection program commensurate with the scope and extent of our licensed activities and sufficient to ensure compliance with applicable NRC regulations. We will review this radiation protection program content and its implementation annually. *We shall establish a Radiation Safety Committee consisting of the Radiation Safety Officer and at least two authorized users. A quorum to conduct a meeting shall include the RSO and two Committee Members.*

b) We shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are **as low as is reasonably achievable. (ALARA)**. *We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2. Except that : A) The formal reviews by the Radiation Safety Committee and by the Radiation Safety Officer shall only be conducted annually. and B) The investigational levels in table I shall refer to the effective dose equivalent which includes the external and internal doses. The summation of the external and internal doses shall be pursuant to 10 CFR 20.1202. Also for doses to the members of the public from external and internal sources of radiation the Investigational level I shall be 25 percent of the applicable limits and investigational level II shall be 50 percent of the applicable limits.*

c) Records of the Radiation Protection Program

The Radiation Safety Officer shall maintain the records of the radiation Protection Program as required by 10 CFR 20 Subpart L and also any records as required by 10 CFR 19 and 30.

d) Radiation Detection Equipment

The following radiation detection equipment shall be available:

Beckman Model 6000 Liquid Scintillation Counter.  
Ludlum Model 3 meter with Model: 44-9 GM probe.

Survey instruments shall be calibrated annually and after any major repairs. Calibration shall be by a company licensed by the NRC to provide calibration services. Laboratory instruments used to quantify radioactivity assay measurements shall be calibrated using commercially available or NIST



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traceable standards. Examples of licensed calibrators are Radiation Management Corporation, Wilmington, Delaware 19809; Ludium Measurements Corporation, Sweetwater, Texas , 79556 and RSO Inc. P. O. Box 1526 Laurel, MD

e) Personnel Monitoring

Personnel monitoring shall be provided pursuant to 10 CFR20. 1502. In addition, extremity monitors (rings) shall be worn by personnel requiring monitoring when handling greater than one millicurie of P-32 in experimental procedures.

Personnel monitoring devices shall be changed at least quarterly.

A dosimetry processor which complies with 10 CFR 20.202. (c) shall be used.

Bioassay shall be performed in the event of a suspected intake of activity from a spill or accident. A screening bioassay shall be performed by assaying urine collected within 24 hours of the event. Positive bioassays will be submitted to our Radiation Safety consultant for independent verification and dose calculation.

f) Radioactive Spills and Emergencies

We will establish and implement the model spill procedures published in appendix J to Regulatory Guide 10.8 Revision 2. Spills involving greater than 5 millicuries will be considered major spills.

g) Procedure for Ordering RAM

The Radiation Safety Officer or his designee shall authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that the possession limits are not exceeded.

The RSO or his designee will establish and maintain a system for ordering and receiving radioactive material. The system will contain, at a minimum, the following information:

1. Written records that identify the authorized user, the isotope, chemical or physical form, activity , date of order and supplier for each order.
- 2) A radio nuclide usage form for each order to record usage and disposition.
- 3) The provision to sum orders and dispositions to maintain a running inventory of each radio nuclide on hand.

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4) The above records will be checked to confirm that all material received was ordered through proper channels.

h) Procedure for Receiving Packages

For deliveries during normal hours the RSO will instruct carriers to deliver directly to a designated person in a specified area. The package shall be checked for damage and if damaged notify the RSO and ask the carrier to remain until it can be determined that neither the driver nor the truck is contaminated.

Deliveries will not be received after hours.

i) Procedure for Monitoring Packages

Packages will be monitored pursuant to 10 CFR 20. 1906 and appropriate agencies notified if radiation or contamination levels are in excess of regulatory limits.

j) Procedure for Opening Packages

Packages shall be opened pursuant to 10 CFR 20.1906.

We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2 except for item 2. (c) . The exposure rates from packages will be measured as required by 10 CFR 20. 1906. Also packages shall be wipe tested pursuant to 10 CFR 20. 1906.

k) Inventory System

We will establish an inventory system that documents the receipt, use and disposition of all radioactive materials. The system shall permit the determination of the total activity on hand at any time, by radio nuclide, as well as the monthly and total annual sewer disposition.

l) Survey program

We will establish the following survey program:

- 1) All areas where radioactive material is used or stored will be surveyed pursuant to 10 CFR 20.1501.
- 2) All areas where radioactive material is used or stored will be surveyed at least quarterly.
- 3) The action levels for decontamination are: Unrestricted areas 200 dpm per 100 sq cm ; restricted areas 2,000 dpm per 100 sq cm. Areas exceeding these levels shall be decontaminated and resurveyed.



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The action levels for radiation levels are 5 millirem per hour for restricted areas and 0.5 millirem per hour for unrestricted areas. Shielding shall added if levels are exceeded.

4) Individual users shall be required to survey for contamination, regularly used laboratories where activity greater than Appendix C 10 CFR part 20.1001 to 20. 2401 is handled by an employee at one time. The survey frequency shall be at least monthly. Records of survey results shall be kept per 10 CFR 20.2103 using units as required by 10 CFR 20. Levels exceeding the trigger levels shall be decontaminated. The RSO shall be notified if decontamination fails to reduce the levels below the trigger levels.

5) Individual users will be encouraged to survey themselves, their lab coats and the facilities they were using whenever they finish a procedure using any level of radioactivity. They will be required to survey daily or whenever they finish a procedure where activity greater than Appendix C 10 CFR part 20.1001 to 20. 2401 is regularly handled. Records of these surveys are not required.

m) General radiation Safety Practices

We will establish the following general rules for the use of Radioactive Material (RAM):

1. Protective clothing such as lab coats and disposable gloves shall be worn when using RAM or working in areas where RAM is handled.
2. Personnel shall not eat, drink, smoke or store food in areas where RAM is used or stored.
3. Minimize contamination or exposure by careful experimental planning, dry runs, shielding and monitoring.
4. RAM shall be used, stored and transported in containers designed to minimize spills.
5. Secure all radioactive materials when not under constant surveillance and immediate control of the authorized user.
6. Use protective bench coverings, monitor and decontaminate as you work to control contamination.
7. Use fume hoods or glove boxes if potential for airborne contamination exists.
8. Dispose of radioactive waste only in designated, labeled and properly shielded receptacles. Radioactive waste should be minimized by careful experimental design.

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9. Wear personnel dosimeter, if issued, at all times in areas where RAM is used or stored.

10. Hands should be thoroughly washed and appropriately monitored before leaving RAM work areas after having handled RAM.

**Item 11**

Waste Management

We will establish and implement the general and model procedures for waste disposal, including the storage for decay of radio nuclides with half lives less than 65 days, that were published in appendix R to regulatory Guide 10.8 Revision 2.

In addition we also request to be able to store for decay and disposal as non radioactive waste, S-35 waste using the same procedures as noted in appendix R to regulatory Guide 10.8 Revision 2. We will use a Ludlum model 3 survey meter equipped with a model 44-9 probe, or a survey meter with the equivalent sensitivity for the radio nuclides in use in this facility, to monitor each bag of waste.

All radio nuclides used at this facility, except H-3 and C-14, will be stored for decay. Personnel will be instructed to segregate waste by radionuclide at the time it is generated and to place it into the containers specifically labeled for that radio nuclide. If experimental procedures require dual radio nuclide use the waste shall be labeled as such and shall be stored in the containers identified for the radio nuclide with the longest half-life. Personnel will also be instructed in the specific records and labels required and of the importance of following all rules relating to the use and disposal of radioactive material. Instructions will also cover the need to design experiments to minimize waste and to avoid mixing waste with other hazardous materials. Sample instructions are given in Appendix C. We reserve the right to modify these instructions provided that the modification does not alter the radiation safety aspects of the instructions.

All waste stored for disposal by decay will be maintained separately from other radioactive materials, i. e. In a separate clearly labeled container within the waste storage area.

The wastes will be stored in shielded containers within a locked enclosed area within the facility. Access to this area will be limited to the authorized users. See Appendix B for a diagram of the area.

**Information needed in support of authorization for extended interim storage of low level radioactive waste. (Per IN 90-09)**

**1. Identify Waste to be stored**

**Lexin Pharmaceutical Corporation**  
**Rock Plaza III, 111 Rock Road**  
**Horsham, PA 19044-2310**

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Waste will be class A solid waste  
Waste activity on hand will not exceed 50% of the license limits  
Maximum volume of waste generated - 6 cubic feet/year  
No additional permits will be required.

**2. Plans for Final Disposal**

Onsite storage will begin as soon as we have H-3 or C-14 waste.  
We belong to the Appalachian Compact and the date for accepting waste is projected to be 1999.  
We will ship waste as soon as it is feasible to do so.  
Transfer to a NRC licensed disposal facility .

**3. Description of Storage Area**

See Appendix B for a plan of the waste storage area.

Waste will be stored within the facility in a locked room ( 4 ft by 12 ft) with access limited to authorized users or persons directly supervised by authorized users.

This area has capacity for storing over 75 cubic feet of waste.

The storage area is covered by the facility heat , ventilation, fire alarm and security systems and is also equipped with a hand held fire extinguisher.

We do not expect airborne releases from the wastes stored in this area and no air monitors are planned. The ventilation for this area is part of the facility air handling system.

**4. Packaging and container Integrity.**

Materials will be stored in containers that are suitable for interstate transport. For example 5, 30 or 55 gallon plastic or steel drums . These containers are not expected to deteriorate during the storage period.

**5&6. Radiation Protection/Training**

The waste containers and the storage area will be included in the quarterly radiation surveys of the facility.

Suitable shielding will be used to reduce levels outside the storage areas to levels acceptable for unrestricted areas.

Complete records of waste collection, storage and disposal shall be kept.

Only authorized individuals or trained individuals working under the direct supervision of an authorized user will handle the waste.

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See also the Facility Radiation Protection Program which also applies to the waste storage area.

We will train all persons using the extended interim storage for radioactive materials in the proper procedures for packaging, handling, placement, inspection, surveying and emergency response for these materials. The training will be by lecture and will be conducted by personnel under the direction of the RSO.

**7&8.      Financial Assurance and Emergency Preparedness**

Not applicable

**Item 12.**

3 M.      \$1400.00 enclosed      Also See attached form(313)

**Item 13**

Signature-- See Attached Form      NRC (313)

Lexin Pharmaceutical Corporation  
Rock Plaza III, 111 Rock Road  
Horsham, PA 19044-2310

Form NRC 313( 6/93) Application for Materials license  
APPENDIX A

**TRAINING AND EXPERIENCE OF AUTHORIZED USER.**

Jennifer Gold Thallmayer, Ph. D.

**Education:**

- a) Ph.D. (1987) Biological Chemistry, Univ. of North Carolina
- b) B. A. (1979) Kansas State University

**Work with Radionuclides:**

- 1) Neose Pharmaceuticals 1991-1993
- 2) Univ. of Penna. 1990-1991
- 3) Medical College Penna. 1987-1990
- 4) Univ. of N. Carolina 1981-1987
- 5) Kansas State 1979-1980 )

**LIST TRAINING (FORMAL COURSES) PERTINENT TO RADIATION SAFETY**

Type of training	Where trained	Duration of training* clock hours
Principles of radiation protection	1, 2, 3, 4, 5 above	10/over 500 hrs
Radioactivity measurement	1, 2, 3, 4, 5 above	50/over 500 hrs
Physics & mathematics basic to use and measurement of radioactivity	1, 2, 3, 4, 5 above	100/over 500 hrs
Biological effects of radiation	1, 2, 3, 4, 5 above	20/over 500 hrs

\* Lecture or lab/ Supervised on the job

**EXPERIENCE WITH RADIATION**

Isotope	mCi Used	Location	Clock Hours	Type of use
H-3	2	1,2,3,4 above	over 500	**
C-14	1	1,2,3,4 above	over 500	**
S-35	5	4 above	over 500	**
P-32	5	4 above	over 500	**

\*\*Molecular biology procedures , biological chemistry, synthesis

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Rock Plaza III, 111 Rock Road  
Horsham, PA 19044-2310

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APPENDIX A

TRAINING AND EXPERIENCE OF AUTHORIZED USER.

Arthur Berger Jr., B.A.

Education:

a) B. A. (1991) Psychobiology, Beaver College, Glenside, PA

Work with Radionuclides:

- 1) Merck Research labs 1993-1994
- 2) Sterling Winthrop 1992-1993
- 3) Center for Molecular Medicine 1991-1992

LIST TRAINING (FORMAL COURSES) PERTINENT TO RADIATION SAFETY

Type of training	Where trained	Duration of training* clock hours
Principles of radiation protection	1, 2, 3, above	10/10 hrs
Radioactivity measurement	1, 2, 3, above	10/10 hrs
Physics & mathematics basic to use and measurement of radioactivity	a, 1, 2, 3, above	50/10 hrs
Biological effects of radiation	1, 2, 3, above	10/10 hrs

\* Lecture or lab/ Supervised on the job

EXPERIENCE WITH RADIATION

Isotope	mCi Used	Location	Clock Hours	Type of use
H-3	2	2 above	over 100	**
P-32	1	2,3 above	over 100	**
S-35	5	2,3 above	over 100	**
Y-99	5	2 above	over 100	**
I-125	1	3	over 100	
I-131	1	3	over 100	

\*\*Molecular biology procedures , monoclonal antibody studies



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APPENDIX A

**TRAINING AND EXPERIENCE OF AUTHORIZED USER.**

Howard Sands, Ph. D.

**Education:**

- a) Ph.D. (1969) Pharmacology, Case Western Reserve Univ.
- b) Post doc.. (1971) Renal Pharmacology, Northwestern University

**Work with Radionuclides:**

- 1) Dupont/Merck, Dupont PA, New England Nuclear/Dupont 1981-1994
- 2) National Jewish Hosp. Denver 1971-1981

**LIST TRAINING (FORMAL COURSES) PERTINENT TO RADIATION SAFETY**

Type of training	Where trained	Duration of training* clock hours
Principles of radiation protection	1, 2, above	10/over 500 hrs
Radioactivity measurement	1, 2, above	20/over 500 hrs
Physics & mathematics basic to use and measurement of radioactivity	1, 2, above	20/over 500 hrs
Biological effects of radiation	1, 2, above	10/over 500 hrs

\* Lecture or lab/ Supervised on the job

**EXPERIENCE WITH RADIATION**

Isotope	mCi Used	Location	Clock Hours	Type of use
H-3	2	1 above	over 500	**
C-14	1	1 above	over 500	**
Ca-45	5	1 above	over 100	**
P-32	5	1 above	over 500	**
I-125	1	1 above	over 500	**
In-111	1	1 above	Over 500	**
Tc 99m	10	1 above	over 100	**

\*\*Molecular biology procedures , biological chemistry, synthesis

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APPENDIX A

**TRAINING AND EXPERIENCE OF AUTHORIZED USER.**

James Jea-Huang Huang, Ph. D.

**Education:**

- a) Ph.D. (1982) Microbiology/Biochemistry, North Carolina State Univ.
- b) M.S. (1973) Agriculture Chemistry/Applied Microbiology, Taiwan Univ.
- c) B.S. (1971) Agriculture Chemistry/Soil Microbiology, Chung Hsing Univ.

**Work with Radionuclides:**

- 1) Sterling Winthrop 1988 -1993
- 2) Dupont Glenolden, PA 1985-1988
- 3) Centocor Inc. Malvern, PA. 1984-1985
- 4) Purdue Univ. 1982-1984

**LIST TRAINING (FORMAL COURSES) PERTINENT TO RADIATION SAFETY**

Type of training	Where trained	Duration of training* clock hours
Principles of radiation protection	1, 2, 4 above	50/over 200 hrs
Radioactivity measurement	a, 1, 2, 4 above	50/over 200 hrs
Physics & mathematics basic to use and measurement of radioactivity	a, b, 1, 2, 4 above	100/over 200 hrs
Biological effects of radiation	1, 2, 4 above	20/over 500 hrs

\* Lecture or lab/ Supervised on the job

**EXPERIENCE WITH RADIATION**

Isotope	mCi Used	Location	Clock Hours	Type of use
P-33	2	1,2 above	over 500	**
P-32	5	1,2,4 above	over 500	**
S-35	5	1, 2 above	over 500	**
I-125	0.1	3 above	over 50	**

\*\*Molecular biology procedures , sequencing, DNA probes

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APPENDIX A

**TRAINING AND EXPERIENCE OF AUTHORIZED USER.**

Stephen D. Burrows, M. S.

**Education:**

- a) M. S. (1989) Biology Eastern Michigan Univ.
- b) B. A. (1980) Biology Tri-State Univ.

**Work with Radionuclides:**

- 1) SmithKline Beecham Pharmaceuticals 1991-1994
- 2) G.D. Searle 1989-1991
- 3) Warner-Lambert/Park Davis 1983-1989
- 4) Indiana Univ. Med. Center 1980-1983

**LIST TRAINING (FORMAL COURSES) PERTINENT TO RADIATION SAFETY**

Type of training	Where trained	Duration of training* clock hours
Principles of radiation protection	1, 2, 3, above	10/over 50 hrs
Radioactivity measurement	a, b, 1, 2, 3, above	20/over 100 hrs
Physics & mathematics basic to use and measurement of radioactivity	a, b, 1, 2, 3, 4, above	100/over 100 hrs
Biological effects of radiation	a, 1, 2, 3, 4, 5 above	20/over 100 hrs

\* Lecture or lab/ Supervised on the job

**EXPERIENCE WITH RADIATION**

Isotope	mCi Used	Location	Clock Hours	Type of use
H-3	2	1,2,3 above	over 500	**
C-14	1	1,2,3 above	over 100	**
S-35	1	1,2,3 above	over 100	**
P-32	5	2, 3 above	over 200	**
I-125	1	2, 3 above	over 200	**

\*\*Molecular biology procedures , RIA , synthesis

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Rock Plaza III, 111 Rock Road  
Horsham, PA 19044-2310

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APPENDIX A

**TRAINING AND EXPERIENCE OF AUTHORIZED USER.**

Christopher P. Phillips, M. S.

**Education:**

- a) M. S. (1984) Biology . Univ. of South Florida
- b) B. S. (1977) Biology . Univ. of South Florida

**Work with Radionuclides:**

- 1) Sterling Winthrop 1989-1993
- 2) Centocor, Malvern, PA 1985-1988

**LIST TRAINING (FORMAL COURSES) PERTINENT TO RADIATION SAFETY**

Type of training	Where trained	Duration of training* clock hours
Principles of radiation protection	1, 2, above	10/over 50 hrs
Radioactivity measurement	a, b, 1, 2, above	20/over 100 hrs
Physics & mathematics basic to use and measurement of radioactivity	a, b, 1, 2, above	100/over 100 hrs
Biological effects of radiation	a, 1, 2, above	20/over 100 hrs

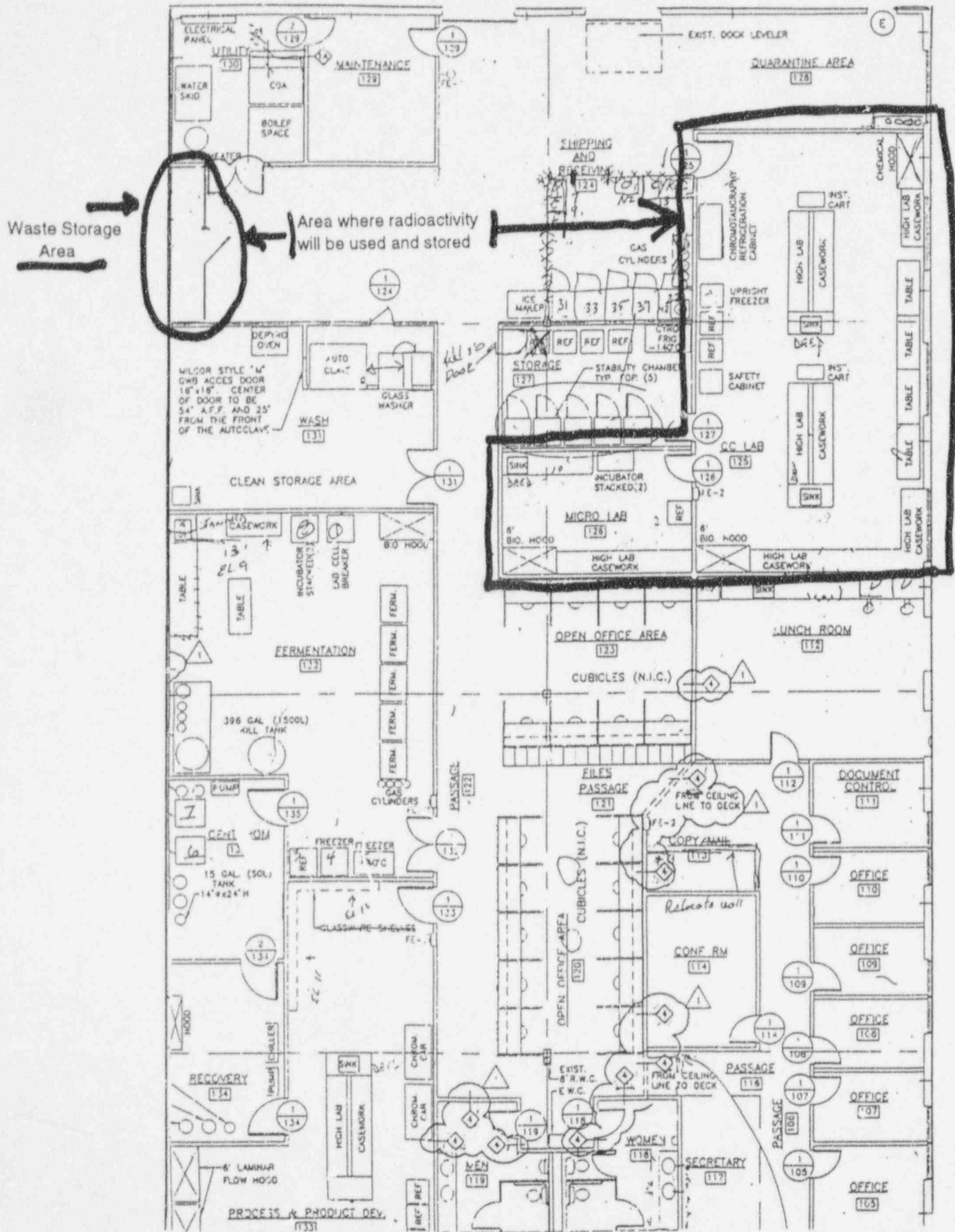
\* Lecture or lab/ Supervised on the job

**EXPERIENCE WITH RADIATION**

Isotope	mCi Used	Location	Clock Hours	Type of use
Tc 99m	2	2 above	over 100	**
In-111	1	2 above	over 100	**
I-125	1	1,2 above	over 200	**
Y-90	2	1 above	over 200	**

\*\*Molecular biology procedures synthesis

Application for Materials license  
APPENDIX B



121325

Lexin Pharmaceutical Corporation  
Rock Plaza III, 111 Rock Road  
Horsham, PA 19044-2310

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## APPENDIX C

Instructions for employees concerning the segregation of radioactive wastes:

### WASTE DISPOSAL

The disposal of radioactive wastes is in a period of transition and we are currently required to store short lived radio nuclides for at least ten half lives for disposal by decay-in-storage and also to store longer lived waste, H-3 and C-14, until such time as a commercial disposal facility becomes available. To accomplish this it is extremely important to segregate wastes as they are generated into properly labeled containers and to follow the disposal procedures listed below. Failure to follow these procedures will result in restrictions on your use of radioactivity. If you have any questions concerning waste disposal contact Dr. James J. Huang

### LONG TERM STORAGE

Segregate the H-3 and C-14 waste by isotope, place an identify number on each waste bag and place into proper secondary storage containers in the waste room. Add the following information to the storage container log : bag ID number, radionuclide, activity , date placed in storage and name of authorized user.

### STORAGE FOR DISPOSAL BY DECAY

The following radio nuclides may be disposed by decay-in-storage; P-32, P-33, I-125, S-35 . The following rules apply when using this method of disposal:

- a) Keep all wastes segregated by radionuclide as they are generated and do not mix wastes.
- b) Clearly label each waste container by radionuclide.
- c) When waste container is full, seal and identify the container. Generate a record that identifies the waste container , the radionuclide, the date sealed and the authorized user.
- d) The container must be stored in the waste storage area for 10 half lives.
- e) Prior to disposal monitor all sides of the container with an appropriate survey meter in an area free of radiation levels above background. The container can be discarded if the meter measures no radiation levels above background. An appropriate meter is a Ludlum model 3 equipped with a 44-9 probe ( Pancake GM) The MDA for this survey method is less than 0.01 microcuries.
- f) All radiation labels in or on the container must be obliterated prior to disposal.
- g) A record containing the following must be generated: Container ID number, Date sealed, date disposed, survey meter identity , survey results, person surveying.

121325



LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)  
INFORMATION FROM LTS

```

: PROGRAM CODE: 03620
: STATUS CODE: 3
: FEE CATEGORY: -----
: EXP. DATE: 0
: FEE COMMENTS: -----
: DECOM FIN ASSUR REQD:
:

```

## A. REGION

APPLICANT/LICENSEE: LEXIN PHARMACEUTICAL CORPORATION  
RECEIVED DATE: 950213  
DOCKET NO: 3033799  
CONTROL NO.: 121325  
LICENSE NO.:  
ACTION TYPE: NEW LICENSEE

AMOUNT: \$ 1400.00  
CHECK NO.: 001219

SIGNED Mr. A. Perkins  
DATE 2/22/95

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

1. FEE CATEGORY AND AMOUNT: 3m 8/400

AMENDMENT  
RENEWAL  
LICENSE

3. OTHER

SIGNED James Brown  
DATE 2/18/95