

MATERIALS LICENSE

Amendment No. 01

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 1, Parts 30, 31, 32, 33, 34, 35, 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

1. Medarex, Incorporated

2. P.O. Box 992  
1545 Rt. 22 East  
Annandale, New Jersey 08801-0992

In accordance with the application dated June 12, 1997,  
3. License number 29-30119-01 is amended in its entirety to read as follows:

4. Expiration date February 28, 2004

5. Docket or Reference No. 030-33421

6. Byproduct, source, and/or special nuclear material

7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

A. Phosphorous 32  
B. Phosphorous 33  
C. Chromium 51  
D. Iodine 125

A. Any  
B. Any  
C. Any  
D. Labelled compounds

A. 5 millicuries  
B. 5 millicuries  
C. 10 millicuries  
D. 5 millicuries

9. Authorized use

A. through D. 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 1545 Route 22 East, Annandale, New Jersey.

11. A. Licensed material shall be used by, or under the supervision of, Tibor Keler, Ph.D., Robert Graziano, Ph.D., Theresa Morely, Chezian Somasundaram, Ph.D., or Aditya Mandal, Ph.D.

B. The Radiation Safety Officer for this license is Tibor Keler, Ph.D.

12. Licensed material shall not be used in or on human beings.

13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.



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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

29-30119-01

Docket or Reference number

030-33421

Amendment No. 01

14. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 65 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.
  - 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.
15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. 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 December 20, 1993
  - B. Application dated June 12, 1997

JUN 25 1997

Date \_\_\_\_\_

For the U.S. Nuclear Regulatory Commission

**ORIGINAL SIGNED BY:**

By **JAMES M. BONDICK**

Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

JUN 25 1997

Yashwant Deo  
Vice President, Operations  
Medarex, Incorporated  
1545 Route 22 East  
P.O. Box 992  
Annandale, New Jersey 08801-0992

Dear Mr. Deo:

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. Your new expiration date is stated in Item 4 of the license.

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.

Your application should have been signed by a management representative rather than Radiation Safety Officer. Note also that a management representative should sign all future correspondence that requests a change in your license.

Thank you for your cooperation.

Sincerely,

**ORIGINAL SIGNED BY:  
JAMES M. BONDICK**

James M. Bondick  
Health Physicist  
Division of Nuclear Materials Safety

License No. 29-30119-01  
Docket No. 030-33421  
Control No. 124669

Enclosure:  
Amendment No. 01

OFFICIAL RECORD COPY ML 10

Y. Deo  
Medarex, Incorporated

-2-

DOCUMENT NAME: R:\WPS\MLTR\L2930119.01

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	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	JBondick/jmb <i>B</i>						
DATE	06/17/97	06/ /97	06/ /97	06/ /97	06/ /97	06/ /97	06/ /97

OFFICIAL RECORD COPY

# MEDAREX

030-33421

1545 Route 22 East  
PO Box 992  
Annandale, NJ 08801-0992  
908•713•6000 Fax: 908•713•6013

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

To the Licensing Assistant Team:

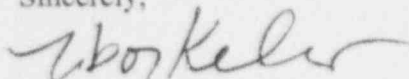
Please find enclosed an amendment to our current material license # 29-30119-01. The purpose for this amendment is to relocate our radiation laboratory within our facility, and to cover 2 additional laboratories for use of radioactive materials under the conditions specified by our current license. Diagrams of our facility and the proposed changes are enclosed for your review.

The laboratory which is currently approved for radioactive use will be shut down (no further use or purchase of radioactive materials) on June 24, 1997. Shortly thereafter, the equipment and room will be decontaminated and surveyed by wipe tests and Geiger-Muller probes. The results of surveys and decontamination activities will be recorded in our files. We have in our possession approximately 3.5 mCi of  $^{51}\text{Cr}$  for decay on site. The radioactive waste is behind lead shielding, and would remain in the room until we received approval of our amendment to move it to one of the newly licensed laboratories. All personnel which may have access to radioactive materials areas will be properly trained, and areas storing radioactive materials will be appropriately labeled.

The new laboratories to be issued licensing for radioactive use are on the same floor as the existing laboratory, and are surrounded only by laboratories. This move has been solely prompted due to a redesign for practicality and increased laboratory space. No additional amendments for this license are being filed, and we will abide by all of the conditions and provisions in our existing license. Due to our low quantity and usage of radioactive materials, and that this amendment only involves changing of rooms within the same facility, we hope this amendment can be processed rapidly. We would like to be able to move the radioactive waste by July 1, 1997 and start radioactive materials usage in the new laboratories on July 15, 1997.

We have enclosed a check for \$610.00 for the amendment filing fee. This price was quoted to me by Brenda Brown on 6/12/97. Please notify me if there are any questions or concerns regarding this matter. My telephone number is: (908) 713-6000 x309, or e-mail : tkeler@injersey.com.

Sincerely,



Tibor Keler, Ph.D.  
R.S.O.

OFFICIAL RECORD COPY ML 10

124669  
JUN 13 1997



## APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 8 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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. 030-33421

## APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001

## 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:

LICENSING ASSISTANT SECTION  
NUCLEAR MATERIALS SAFETY BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO  
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,  
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION II  
101 MARIETTA STREET, NW, SUITE 2900  
ATLANTA, GA 30323-0199

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 JURISDICTIONS.

## IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,  
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION III  
796 ROOSEVELT ROAD  
GLEN ELLYN, IL 60137-5927

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW  
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING,  
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S.  
TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION V  
1450 MARIA LANE  
WALNUT CREEK, CA 94596-5368

## 1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐  
☒  
☐

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER 29030119-01

C. RENEWAL OF LICENSE NUMBER

## 2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

Medarex, Inc.  
1545 Route 22 East  
Annandale, NJ 08801-0992

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

Same as 2

## 4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Tibor Keler

TELEPHONE NUMBER  
908-713-6000, Ext. 309

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 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 \$610.00
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, 36, 39 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.	

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Yashwant M. Deo

SIGNATURE

DATE

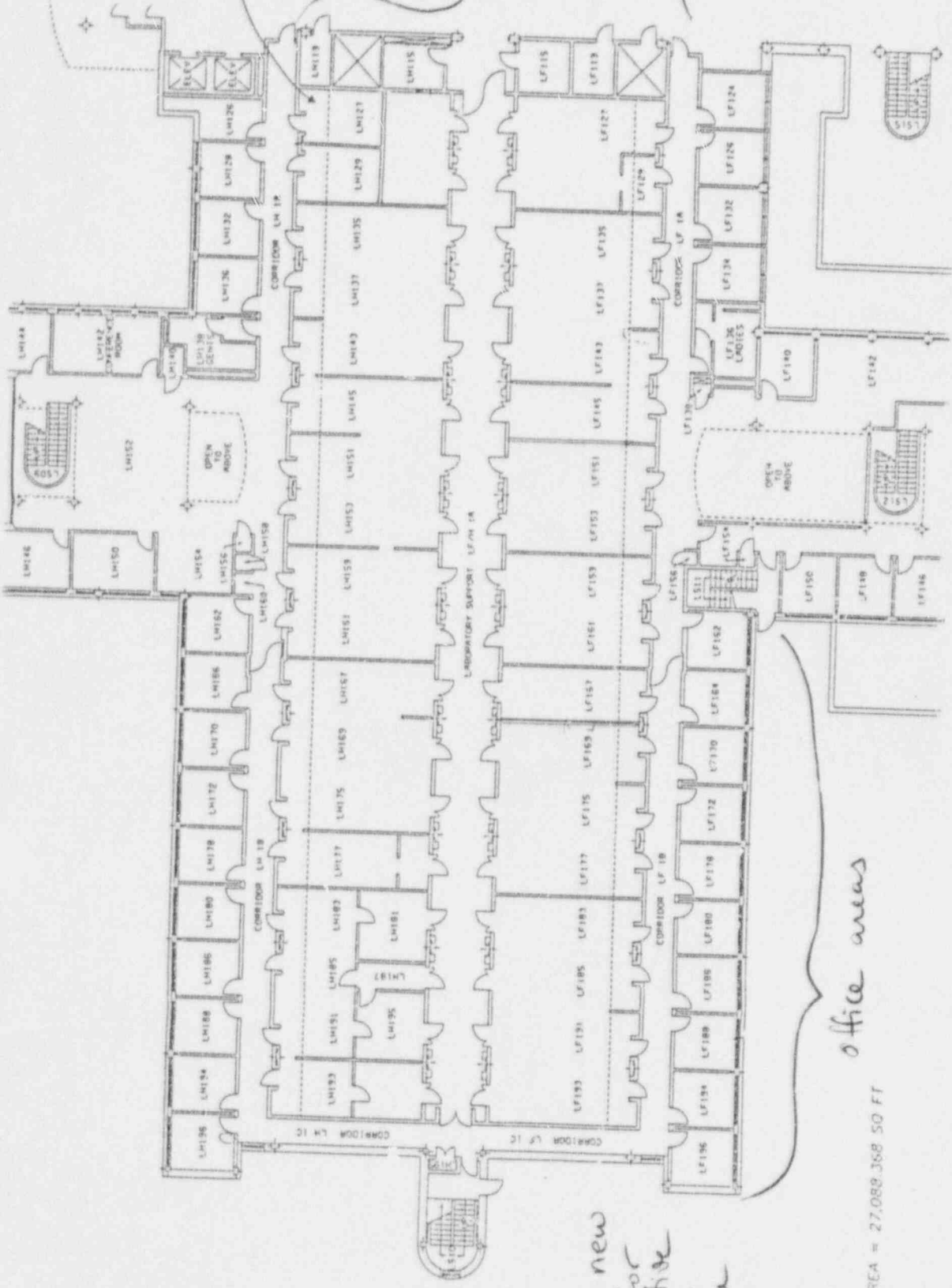
6/12/97

## FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

LH 127  
USE & STORAGE  
OF RADIOACTIVE  
MATERIALS  
Currently covered  
under license  
#23-30119-01

Laboratory  
space

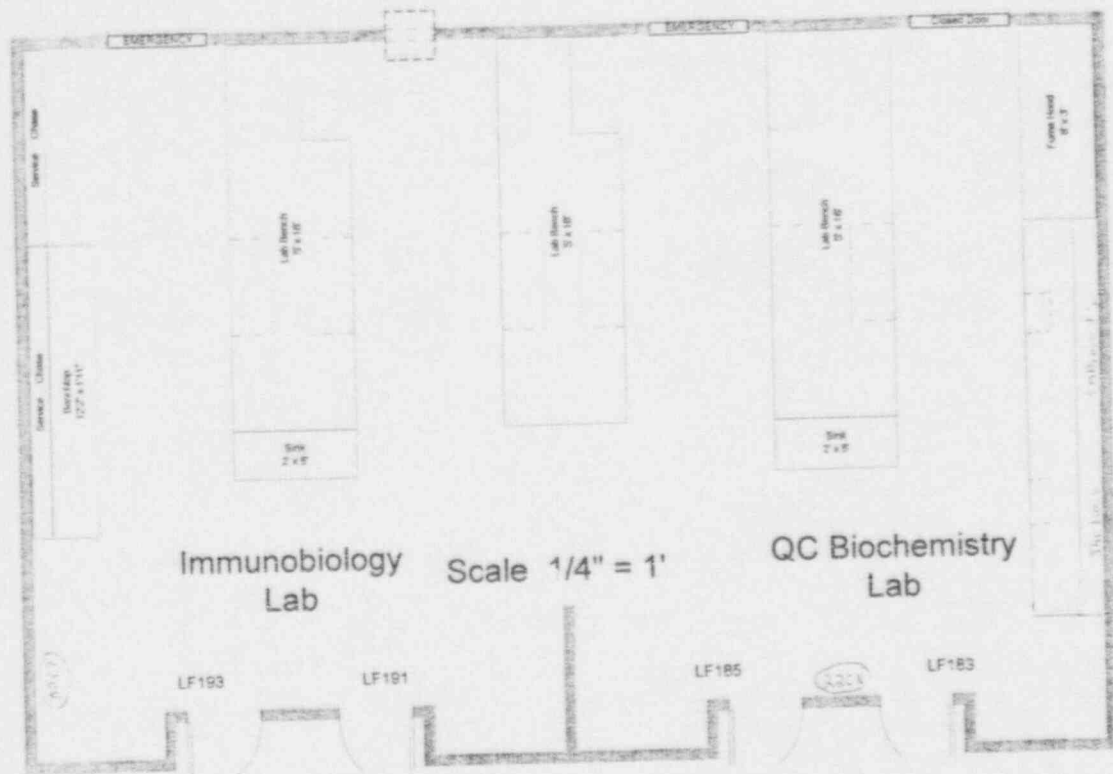


Proposed new  
areas for  
radioactive  
storage

Office areas

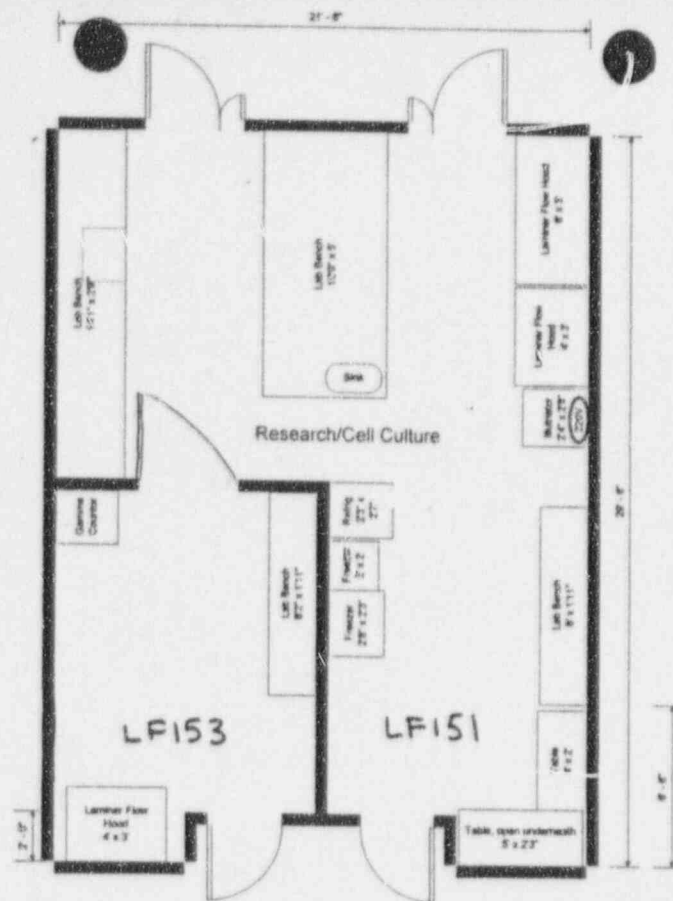
AREA = 27,088.368 SQ FT

124669



124669





124669



BETWEEN:

License Fee Management Branch: ARM  
and  
Regional Licensing Sections

OR LFMS USE)  
INFORMATION FROM LTS

Program Code: 03620  
Status Code: 0  
Fee Category: 3M  
Exp. Date: 20040228  
Fee Comments: \_\_\_\_\_  
Decom Fin Assur Req'd: N  
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: MEDAREX, INC.  
Received Date: 970613  
Docket No: 3033421  
Control No.: 124669  
License No.: 29-30119-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: \$610.00  
Check No.: 2954

3. COMMENTS

Signed Brown R. J.  
Date 6/16/97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: 3m \$610

2. Correct Fee Paid. Application may be processed for:

Amendment ☒  
Renewal ☐  
License ☐

3. OTHER \_\_\_\_\_

Signed \_\_\_\_\_  
Date \_\_\_\_\_

NOT JUN 19 AM 7:20

Log June 11  
Renewal ☐  
Check No. 2954  
Amount \$610  
Fee Category 3m  
Type of Fee AMD  
Date Check Rec'd 6/23/97  
Date Completed \_\_\_\_\_  
By: BB