



351 Phoenixville Pike
Malvern, PA 19355-1046
Phone 610.296.8660
Fax 610.296.8661
www.neotropix.com

July 10, 2006

Attention: LAT
Division of Nuclear Materials Safety
U.S. NRC
Region I
475 Allendale Road
King of Prussia, PA 19406

Br. 2

Subject: Neotropix Inc.
Request to Increase Authorized License Limits
NRC License No. 37-31129-01 030 37137
IES Project No. EHS06619.01

RECEIVED
REGION I
2006 JUL 11 PM 12:11

To Whom It May Concern:

Neotropix Inc (Neotropix) of Malvern, Pennsylvania, NRC License No. 37-31129-01, would like to request the NRC increase our license limit for S-35 as detailed below and in the attachment.

Neotropix is requesting this increase to allow us to perform additional studies needed to advance our research without nearing or potentially exceeding our current limit. The purpose(s) for which licensed material will be used will remain the same. We will be utilizing recent hires in addition to our existing users to perform additional studies. The recent hires have experience with radionuclide use and have been trained in accordance with our license conditions and NRC requirements. They will be working under our current authorized users.

Considering the addition of new staff and the relatively low energy of S-35 we do not expect existing staff exposure to increase significantly. Nor do we plan for the maximum amount currently used at one time to increase. We simply want to ensure our limits allow for an increased number of studies as well as room to perform decay in storage.

Should you have any questions regarding this request, please feel free to contact Jessica Leonard of IES Engineers at 610-828-3078. If not, we look forward to receiving an updated version of our license.

Sincerely,

Paul Hallenbeck, Ph.D.
President and CSO

enclosure

cc: L. Hales, Neotropix
J. Leonard, IES

139114
NMSS/RGNI MATERIALS-002

ITEM 1

THIS IS AN APPLICATION FOR

B. Amendment to License Number 37-31129-01

ITEM 2

NAME AND ADDRESS OF APPLICANT (INCLUDE ZIP CODE)

Neotropix, Inc.
351 Phoenixville Pike
Malvern, PA 19355

ITEM 3

ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

351 Phoenixville Pike
Malvern, PA 19355

ITEM 4

NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Laura Hales, Ph.D. or Ms. Jessica Leonard (IES Engineers)

TELEPHONE NUMBER

610-296-8660 x 118 (Jessica's phone 610-828-3078)

ITEM 5

RADIOACTIVE MATERIAL

a. Element and Mass Number	b. Chemical and/or physical form	c. Maximum amount to be possessed at any one time
Phosphorus 32	bound/non-volatile	50 millicuries
Phosphorus 33	bound/non-volatile	50 millicuries
Sulfur 35	bound/non-volatile	150 millicuries

ITEM 6

PURPOSE(S) FOR WHICH LICENSE MATERIAL WILL BE USED – NO CHANGE

Neotropix, Inc. (Neotropix) is a research and development company focused on the development and commercialization of virus-based therapeutics for the treatment of cancer and other diseases. Radioactive materials will be used for research and development as defined in Section 30.4 of 10 CFR Part 30 in accordance with the amounts, forms and purposes described above. Animal studies will not be conducted. The increase in license limits reflects our need to perform additional studies to further our research.

Estimated burden per response to comply with this mandatory collection request: 4.4 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. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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.

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:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

03037137

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.

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

- ☐ A. NEW LICENSE
- ☒ B. AMENDMENT TO LICENSE NUMBER 37-31129-01
- ☐ C. RENEWAL OF LICENSE NUMBER _____

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

Neotropix, Inc.
351 Phoenixville Pike
Malvern, PA 19355

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Same as Mailing Address

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Laura Hales, Ph.D.

TELEPHONE NUMBER

(610) 296-8660

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. **See Attached**

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. **See Attached**

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE. **No Change**

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. **No Change**

9. FACILITIES AND EQUIPMENT. **No Change**

10. RADIATION SAFETY PROGRAM. **No Change**

11. WASTE MANAGEMENT. **No Change**

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY **3M** AMOUNT ENCLOSED **\$ N/A**

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
Paul Hallenbeck, Ph.D., President and CSO

SIGNATURE

DATE

9/10/06

FOR NRC USE ONLY

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

This is to acknowledge the receipt of your letter/application dated

7/10/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 37-31129-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 139114.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.