DEPARTMENT OF HEALTH & HUMAN SERVICES

Phone: 870-543-7427
FAX: 870-543-7635
tucker.patterson@fda.hhs.gov

Food and Drug Administration
Jefferson Laboratories

National Center for Toxicological Research
3900 NCTR Road
Jefferson, AR 72079-9502

RECEIVED
OCT - 5 2015
DNMS

September 15, 2015

Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region IV
1600 E. Lamar Boulevard
Arlington, TX 76011-4511

SUBJECT: License Amendment

Dear Sir or Madam:

The U.S. FDA National Center for Toxicological Research (U.S. FDA-NCTR) would like to request the following changes to our Materials License (#03-15093-01):

- Under Condition #11.B., please designate Ms. Kimberly Daniel as the new Radiation Safety Officer for U.S. FDA-NCTR. Ms. Daniel has 15 years of radiation safety experience at the U.S. FDA-NCTR. A copy of her RSO training certificate from Oak Ridge Associated Universities (ORAU) is enclosed.
- As a matter of housekeeping, please remove Conditions #13 and #14 from the license. These conditions applied to an irradiator that was removed from the license subsequent to a previous amendment request.

An Application for Materials License (NRC Form 313) for this license amendment request is enclosed. Please call me at 870-543-7427 or e-mail me at tucker.patterson@fda.hhs.gov if you need additional information.

Thank you,

Tucker A. Patterson, Ph.D., Associate Director
Regulatory Compliance & Risk Management
U.S. FDA National Center for Toxicological Research

Enclosures (2)

PUBLIC
☐ Immediate Release
☑ Normal Release

NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:_____

Reviewer: RDR Date: 10-14-15

589053

ORAU

OAK RIDGE ASSOCIATED UNIVERSITIES

This is to certify that

Kim D. Daniel

has completed

40-HOUR RADIATION SAFETY OFFICER TRAINING COURSE

conducted by Professional Training Programs
of Oak Ridge Associated Universities

This ***26th*** day of ***June, 2009***

at Oak Ridge, Tennessee

Tonya A Bernhardt

Tonya Bernhardt, Health Physicist, CHP

NRC FORM 313 (08-2015) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 09/30/2015**

Estimated burden per response to comply with this mandatory collection request: 4.3 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 FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@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.

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. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
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, 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
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

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, MISSISSIPPI, 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
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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
- [x] B. AMENDMENT TO LICENSE NUMBER 03-15093-01
- [ ] C. RENEWAL OF LICENSE NUMBER

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

U.S. FDA National Center for Toxicological Research
3900 NCTR Road
Jefferson, AR 72079

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

U.S. FDA National Center for Toxicological Research
3900 NCTR Road
Jefferson, AR 72079

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Tucker Patterson, Ph.D.

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(501) 543-7427	(501) 200-7870

BUSINESS EMAIL ADDRESS
tucker.patterson@fda.hhs.gov

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. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY [ ] AMOUNT ENCLOSED $ [ ]

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, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED 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 C RIMINAL 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	SIGNATURE	DATE
William Slikker, Jr., Ph.D., Director, U.S. FDA-NCTR	William Slikker	9/28/2015

FOR NRC USE ONLY

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

589053

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Food and Drug Administration
Jefferson Laboratories
National Center for Toxicological Research
Jefferson, AR 72079-9502

Official Business
Penalty for Private Use, $300

7015 0640 0002 5473 2835

1006113

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OCT - 5 2015
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Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission
1600 E. Lamar Boulevard
Arlington, TX 76011-451

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580053

NRC FORM 532
(1-2012)

U. S. NUCLEAR REGULATORY COMMISSION

DATE

10/13/2015

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
Danny Forbush, Radiation Safety Officer Department of Health and Human Services Food and Drug Administration, National Center for Toxicological Research 3900 NCTR Road Jefferson, AR 72079	03-15093-01
	MAIL CONTROL NUMBER 589053
	LICENSING AND/OR TECHNICAL REVIEWER CH

This is to acknowledge the receipt of your:

☑ LETTER and/or ☐ APPLICATION DATED: 09/15/2015

The initial processing, which included an administrative review, has been performed.

☑ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

☐ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER.** When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

V/10/13

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 03610
Status Code: Pending Amendment
Fee Category: 3L
Exp. Date: 08/31/2017
Fee Comments: 3E ADDED 8/13/92
Decom Fin Assur Reqd: Y

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	HEALTH & HUMAN SERVICES, DEPT. OF
Received Date:	10/05/2015
Docket Number:	3008559
Mail Control Number:	589053
License Number:	03-15093-01
Action Type:	Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Carol L Heer

Date: 10/13/15

B. 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: _____