leidos
Leidos Biomedical Research, Inc.

April 19, 2018

03019755

Licensing Assistance Team
US Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713.

Reference: License Number 19-21091-01 – Amending Practices to Provide/Transfer Radiopharmaceutical Drugs

The purpose of this correspondence is to communicate future practices associated with providing/transferring Radiopharmaceutical Drugs. Currently, we provide/transfer these materials to the National Institutes of Health (NIH) in Bethesda, Maryland. We will have a future need to provide/transfer these materials to umbrella National Cancer Institute (NCI) approved clinical trials at various sites. The NCI is part of the NIH.

We will verify that the recipient is authorized to receive these materials.

Thank-You

Jerry T. Moore
Radiation Safety Officer
Leidos Biomedical Research, Inc.

608405

In the Application dated May 22, 2015 (ML15156B182), under Item 6 (Purpose for Which Licensed Material Will be Used), the following was stated:

"Radiopharmacy – The radiopharmacy laboratory is a full USP-compliant radiopharmaceutical laboratory; one that meets current USP Radiopharmaceuticals for Positron Emission Tomography Compounding (Chapter <823>, USP 28, 2005) and current Pharmaceutical Compounding for Sterile Preparations (Chapter <797>, USP 28, 2005) that will permit the preparation of short-lived radiopharmaceutical drugs for IND (investigational new drug)-directed preclinical studies and for IND-enabled Phase 0 and Phase 1 Clinical Trials.

- *We (NCI Campus at Frederick) will prepare the radiopharmaceutical drugs, but <u>will not</u> administer them to humans.*
- *We will transfer the radiopharmaceutical drugs generated under our NRC License to NIH-Bethesda's NRC License.*
- *The administration of the radiopharmaceutical drugs will occur under the NIH-Bethesda NRC License."*

We are amending our practices as follows:

Radiopharmacy – The radiopharmacy laboratory is a full USP-compliant radiopharmaceutical laboratory; one that meets current USP Radiopharmaceuticals for Positron Emission Tomography Compounding. The Radiopharmacy will provide cGMP doses of investigational PET agents under FDA approved INDs, following 21CFR212.5(b), USP32<823> (2009), to National Cancer Institute (NCI) approved Clinical Trials at various sites.

- *We (NCI Campus at Frederick) will prepare the radiopharmaceutical drug, but <u>will not</u> administer them to humans.*
- *We will transfer the radiopharmaceutical drugs generated under our NRC License to the respective Radioactive Materials Licenses associated with NCI approved Clinical Trials at various sites.*
- *The administration of the radiopharmaceutical drugs will occur under the respective Radioactive Materials Licenses associated with those NCI approved Clinical Trials at various sites.*

NRC FORM 313 **U.S. NUCLEAR REGULATORY COMMISSION**
(10-2017)
10 CFR 30, 32, 33, 34, 35, 36, 37, 39, and 40

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 06/30/2019**

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 Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by 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 CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

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

IF YOU ARE LOCATED IN:

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
- ☑ B. AMENDMENT TO LICENSE NUMBER 19-21091-01
- ☐ C. RENEWAL OF LICENSE NUMBER

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

Jerry T. Moore
Leidos Biomedical - NCI-Frederick - PO Box B
Frederick, Maryland 21702

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

NCI-Frederick
Fort Detrick
Frederick, Maryland 21702

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Jerry T. Moore (RSO)

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(301) 846-1902	N/A

BUSINESS E-MAIL ADDRESS
moorejerry@mail.nih.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 AND 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)
***Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.**

FEE CATEGORY: N/A AMOUNT ENCLOSED: $ 0.00

PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html.

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 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	SIGNATURE	DATE
Jerry T. Moore (RSO)		4/19/18

FOR NRC USE ONLY

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