leidos

Leidos Biomedical Research, Inc.

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October 31, 2018

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

Reference: License Number 19-21091-01 – Amending Currently Approved Radiopharmacy Operations.

The purpose of this correspondence is to communicate proposed changes with respect to currently approved radiopharmacy operations. Our last dose was prepared in the Radiopharmacy on September 29, 2017. Since then, our Authorized Nuclear Pharmacist (ANP) resigned from Leidos on September 8, 2018. Upon notice of ANP resignation, the State of Maryland Department of Health and Mental Hygiene deactivated the associated Pharmacy Waiver. Since then, we have not produced any radiopharmaceutical drugs.

The proposed approach, moving forward, is to operate a cGMP-compliant Radioactive Drug Production Laboratory following Positron Emission Tomography (PET) GMP regulations for the preparation of investigational PET agents under FDA approved Investigational New Drug Applications (INDs). The Radioactive Drug Production Laboratory will occupy the same space (building and rooms) as the former Radiopharmacy. The same (or equivalent) engineering and administrative controls will be employed to ensure that doses to radiation workers and to unrestricted areas are maintained ALARA. In addition, an effluent release monitoring system will continue to be utilized to ensure compliance with effluent release limits.

Apart from the current cessation of radiopharmacy operations, other work within the scope of our radioactive materials license continues.

Thank-You

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

610304

NMSS/RGN1 MATERIALS-002

NRC-accepted language associated with Application (license renewal) dated May 11, 2015 (ML15156B182):

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"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."

Proposed approach:

The Radioactive Drug Production Laboratory will be a cGMP-compliant facility per PET GMP regulation (21CFR212.5(b)) following USP Radiopharmaceuticals for PET Compounding (Chapter <823>, USP 32, 2009) that will permit the preparation of investigational radiopharmaceutical drugs for IND-directed preclinical studies and for IND-approved Clinical Trials, as well as for pre-clinical animal studies. All drugs produced for clinical trials will have IND protocols accepted by the FDA per 10CFR35.100(d) and 10CFR35.200(d) and will be shipped only to authorized users or ANPs.

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"The ANP will supervise the preparation of all radiopharmaceuticals."

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"The ANP will ensure that all authorized users have been appropriately trained and instructed in the safe use of the types and activities of radioactive material used in the pharmacy."

Proposed approach:

Neither an ANP nor an on-site authorized user are required per 10CFR35. The same radiation safety oversight as for any user will be employed.

NRC-accepted language associated with Letter dated April 19, 2018 (ML18117A334)):

"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 drugs but will not 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."*

Proposed language:

The Radioactive Drug Production Laboratory will be a fully cGMP-compliant Radioactive Drug Production Laboratory; one that meets current cGMP requirements for investigational PET drugs. The Laboratory will provide cGMP doses of investigational PET agents under INDs accepted by the FDA, following 21CFR212.5(b), USP32<823> (2009), to National Cancer Institute (NCI) approved Clinical Trials at various sites.

- We (NCI Campus at Frederick) will produce the radiopharmaceutical drugs but will not 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 (10-2017) 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: 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)		10/31/18

FOR NRC USE ONLY

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