

December 12, 2018

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

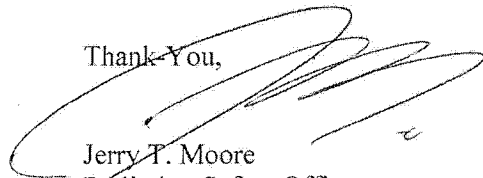
Reference: License Number 19-21091-01 – Amending Currently Approved Radiopharmacy Operations. CONTROL NUMBER 610324

610304

As requested in your November 27, 2018 email, I am confirming that your understanding is correct:

- We will transfer manufactured drugs to medical licensee's for research who are authorized to perform studies under 10 CFR 35.100 and 35.200;
- The drugs will be manufactured in accordance with an Investigational New Drug (IND) protocol accepted by FDA; and
- The dosage level will be less than the amount that require a written directive as stated in 10 CFR 35.40(b).

Thank You,



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

Rec'd. in LAT-12/12/2018

INSTRUMENT MATERIALS-002