UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

May 21, 2020

Brian K. Hardesty, R.Ph.
Vice-President & Radiation Safety Officer
Guardian Pharmacy of Indianapolis Nuclear,
LLC d/b/a Radiopharmacy of Indianapolis,
LLC
6538 Corporate Dr.
Indianapolis, IN 46278

E-mail to: bhardesty@rpofindy.com

SUBJECT: GUARDIAN DBA RADIOPHARMACY OF INDIANAPOLIS REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 618320

Dear Mr. Hardesty:

This letter is in reference to your letter dated March 11, 2020, requesting to amend NRC License No. 13-32637-01MD, and our May 7, 2020 phone conversation discussing that request. Your letter may be found in the NRC's Agencywide Documents and Management System (ADAMS) at Accession No. ML20073J702. In order to continue our review, we need responses the following items within the next 14 days (on or before June 4, 2020):

RADIOACTIVE MATERIAL, INCLUDING PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED:

1. Regarding Subitem No. 8.L. to the referenced license, your request indicated a future need for a possession limit (PL) of 19 curies per source vessel and a total PL of 80 curies. However, based on the Wisconsin Department of Health Services Safety Evaluation Report (SER) 2020-02 (SER) for the NorthStar Medical Radioisotopes LLC Device RadioGenix® System Model 1.0a, Model 1.1, and Model 1.2, dated April 14, 2020, the maximum PL allowed for Radiogenix® System Models 1.1 and 1.2 is "4 source vessels not to exceed 10 curies in each vessel; total not to exceed 50 curies." According to the NRC's Title 10 of the *Code of Federal Regulations* (CFR) Section 35.1000 guidance, "NorthStar Medical Radioisotopes, LLC RadioGenix® Molybdenum-99/Technetium-99m Generator System - Licensing Guidance for Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies," (RadioGenix® 10 CFR 35.1000 guidance) dated January 15, 2020, the NRC may approve possession limits only up to the amount listed on the SER. Accordingly, the PL increase request exceeds what the NRC may approve at this time.

   To request an increase to the PL in Subitem No. 8.L. please provide the following information:

   - ***Revise Item 1 to your request in accordance with the SER, requesting a PL not to exceed: "Four source vessels not to exceed 10 curies per vessel; 50 curies total."***

- ***Revise request by removing Item 4 to your request as SERs are not yet approved for quantities exceeding 10 curies per source vessel and 50 curies total.***

2. Regarding Subitem No. 9.L. to the referenced license, your request indicated the language you would like to have listed on the license. The request omitted the model of RadioGenix® System to be used. According to NRC's RadioGenix® 10 CFR 35.1000 guidance, the "correct model of the NorthStar RadioGenix® System to be used" should be clearly stated. The most recent amendment to the license authorizes the NorthStar RadioGenix™ System Model 1.1. A confirmation that the correct model is limited to the Model 1.1 or updated model information is needed.

   To request the revised language in Subitem 9.L. to the referenced license, please provide one of the following:

   - ***Confirm that the only Correct Model that is needed is the Model 1.1; or***

   - ***Provide an updated Correct Model or list of Correct Models to be used under the license.***

RADIATION SAFETY PROGRAM:

3. Please note that, regarding Item No. 3.b. of your letter, requesting authorization to make future changes to your radiation safety program, the guidance does not allow for revisions to be made based on an approved SER report.

   To request permission to make revisions to existing RadioGenix® System Radiation Safety Programs to conform to future changes in Licensing Guidance and Safety Recommendations from the Manufacturer, please submit a modified request removing references to the SER report and stating that:

   - **The revision is based on a current guidance for RadioGenix System medical use under 10 CFR 35.1000, commercial nuclear pharmacy use posted on the NRC website, or the current operators manual and additional safety recommendations from Northstar;**

TRAINING AND EXPERIENCE:

4. Please note that, regarding Item Nos. 7 and 8.d. to your letter, the NRC cannot authorize the licensee to notify the NRC up to 30 days after allowing an Authorized User (AU) or Authorized Nuclear Pharmacist (ANP), experienced with a different model Radiogenix® than that which the licensee is authorized. If the licensee has possessed the model Radiogenix® more than 30 days prior to adding the new model to its license, the license must be amended prior to allowing that AU or ANP to use the model Radiogenix® with which that individual does not have experience.

To request an authorization to notify NRC Region III within 30 days of allowing the experienced ANP or AU to work at the licensee's facility, please provide:

- ***Revise Items 7 and 8 to your letter in accordance with Items 7 an 8 to the RadioGenix® 10 CFR 35.1000 guidance***

We will continue our review upon receipt of this information. For fastest processing, please submit your response as a pdf file of a signed and dated letter attached to an email at sara.forster@nrc.gov or as a signed and dated facsimile letter at 630-515-1078.

In accordance with 10 CFR 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Document and Management System (ADAMS). ADAMS is accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions regarding this request for additional information, please contact me at 630-829-9892 or sara.forster@nrc.gov.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2020.05.21 15:05:44 -05'00'

Sara A. Forster, Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety, Region III

License No. 13-32637-01MD
Docket No. 030-37428

Mail Control No. 618320