Nemours. Alfred I. duPont Hospital for Children

Br. 1

Medical Imaging Department
1600 Rockland Road
Wilmington, Delaware 19803
P (302) 651-4641 F (302) 651-4476
Nemours.org

September 7, 2017
Region I, Materials Licensing Assistance Branch
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Request for additional clarification for Amendment
License No. 07-16199-02
Docket No. 03019939
Control No. 600553 (Reference) RLJ

Dear Mr. Gallaghar:

Please increase the possession limit for y-90 on the above License No. 07-16199-02. We would like to change the possession limit from 1Ci to 5 Ci, in the event that we would need to treat multiple patients in the same time period.

The Thera-Sphere standard doses are available in six different quantities. We are requesting to increase the ordered doses from 7GBq (189 mCi) per dose to 20 GBq (540mCi) per dose.

ITEM 2: Source/device description: (If applicable list name and manufacturer of radiation delivery device.)

TheraSphere® consists of insoluble glass microspheres where yttrium-90 is an integral constituent of the glass. The mean sphere diameter ranges from 20 to 30 µm. Each milligram contains between 22,000 and 73,000 microspheres. TheraSphere® is supplied in 0.6 mL of sterile, pyrogen-free water contained in a 1.0 mL vee-bottom vial secured within a clear acrylic vial shield. TheraSphere® is available in six standard dose sizes: 3 GBq (81.1 mCi), 5 GBq (135 mCi), 7 GBq (189 mCi), 10 GBq (270 mCi), 15 GBq (405 mCi) and 20 GBq (540 mCi); and also custom dose sizes from 3.5 GBq (94.6 mCi) to 19.5 GBq (527 mCi) in 0.5 GBq (13.5 mCi) increments. The microspheres are delivered into the liver tumor through a catheter placed into the hepatic artery that supplies blood to the tumor. The microspheres, being unable to pass through the vasculature of the liver due to arteriolar capillary blockade, are trapped in the tumor and exert a local radiotherapeutic effect with some concurrent damage to surrounding normal liver tissue. TheraSphere® is manufactured by Nordion Canada Inc. for BTG International Ltd. TheraSphere® is approved as an HUD.

Please contact Kelly Sciole, ksciole@nemours.org or 302-494-7229 for any additional information as needed.
Sincerely,

Paul Kempinski
Enterprise Vice Present, President AIDHC
Nemours/Alfred I. DuPont Hospital for Children
1600 Rockland Road
Wilmington, DE 19899
302-494-7229

CC. Kelly Sciole, C.N.M.T., R.S.O. (Medical)

600856
NMSS/RGN1 MATERIALS-002

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Kelly A. Sciole, CNMT
Radiation Safety Officer
Nemours - Alfred I. duPont Hospital for Children
1600 Rockland Road
Wilmington, Delaware 19803

Date
September 13, 2017

License Number(s)
07-16199-02

Mail Control Number(s)
600856

Licensing and/or Technical Reviewer or Branch
Medical Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 09/07/2017

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 complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

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 I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5239