SSMHealth
CardinalGlennon
Children's Hospital

1465 S. Grand Boulevard
St. Louis, MO 63104-1095
phone: 314-577-5600
cardinalglennon.com

10/30/2017

Materials Licensing Section
Region III
2443 Warrenville Road STE 210
Lisle, Illinois 60532-4352

RE: Amendment Request to 24-32264-01
Docket No. 030-3553
Control No. 600335

Colleen,

This is the information the you have requested for the possession and medical use of SIR-Spheres® (Y-90) resin microspheres, which will be used and possessed in the following location:

SSM Health Cardinal Glennon Children's Hospital
1465 S. Grand Boulevard
St. Louis, MO 63104-1095

Notification:

We commit to the following: A limited specific medical use applicant initially applying for authorization for the medical use of Y-90 microspheres or an existing licensee applying for an amendment may request authorization to notify the NRC in the future that it has permitted an AU to work at this facility without requesting an additional license amendment, provided the following conditions are met:

1) The AU satisfies the training and experience listed in NRC's licensing guidance for Y-90 microspheres; and
2) The AU is currently listed for the same type of Y-90 microsphere use on a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State Licensee of a broad, or a permit issued by a Commission master material license broad scope permittee; and
3) The licensee provides to the NRC a copy of the license or permit on which the AU is listed for the specific microsphere use; and
4) The licensee provide documentation of the above listed conditions to NRC for each AU no later than 30 days after the date that the licensee allows the AU to work as an AU for the specific type of microsphere.

If this authorization is approved, these notification conditions will be incorporated as license conditions in the licensee's license.

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Procedures of Administration

We commit to the following: The licensee shall commit to following the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements, or submit alternative methods.

Administration of Y-90 microspheres must be performed in accordance with the written directive. The licensee shall record the dose or activity delivered to the treatment site. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity and the date.

Termination of Treatment Due to Stasis

We commit to the following: If the administration was terminated of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity, the date, and the signature of an AU for Y-90 microspheres.

Emergent Patient Conditions

We commit to the following: If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the AU should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose or activity, the date, and the signature of an AU for Y-90 microspheres.

Medical Event Reporting

We commit to the following: The licensee shall commit to report any event, except for an event that results from intervention of a patient or human research subject, in which:

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- The administration of byproduct material results in a dose that exceed 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide, or
- The administration of byproduct material: to the wrong individual or human research subject; via the wrong route; or by the wrong mode of treatment; or
- The total dose or activity administered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than the prescribed, or
- The administration of byproduct material results in dose or activity to an organ or tissue other that the treatment site, as documented in the written directive, except for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.

Additionally the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Inventory

We commit to the following: The semi-annual physical inventory of microsphere aggregates (e.g., vials) should include:

- The radionuclide and physical form; and
- Unique identification of each vial in which the microspheres are contained; and
- The total activity contained in each of the vial(s); and
- The location(s) of the vial(s).

The licensee shall retain each semi-annual physical inventory record for three years.

Patient release

We commit to the following: The licensee should commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75.

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Radiation Protection Program Changes

We commit to the following: This guidance may be revised as additional experience is gained regarding the medical use of TheraSphere and SIR-Spheres Y-90 microspheres. A licensee currently authorized to use these products that is committed by license condition to following provisions in a previous revision of this guidance may request a license amendment to commit to following this revision of the guidance instead. The licensee must apply for and receive this license amendment in order to make program changes to conform to this revision of the guidance.

An applicant initially applying for authorization for the medical use of TheraSphere and SIR-Sphere Y-90 microspheres, or a licensee applying for an amendment to conform with this revision of the guidance may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

1.) the revision is in compliance with the regulations; and
2.) the revisions is based upon NRC's current guidance for TheraSphere and SIR-Spheres Y-90 microspheres 35.1000 use posted on the NRC Medical Uses Licensee Toolkit;
3.) the revision has been reviewed and approved by the licensee's Radiation Safety Officer and licensee's management; and
4.) the affected individuals are instructed on the revised program before the change is implemented; and
5.) the licensee will retain a record of each change for five years; and
6.) the record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

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My cell number and e-mail address is included. Please call or e-mail if you have any questions:
Wallace Fuhrman, BA, RSO, CNMT, RT(R)(N)
SSM Radiation Safety Officer
E-mail: wally.fuhrman@ssmhealth.com
Office: (314)268-4012
Cell: (314)795-0891
Fax: (314)577-5399

If you have questions or need additional information, please contact Wallace Fuhrman, BA, RSO, CNMT, RT(R)(N); e-mail: wally.fuhrman@ssmhealth.com; Cell Phone: (314)795-0891. Thank you for your time in processing this amendment request.

I certify that all information submitted is true and correct to the best of my knowledge.

Wallace Fuhrman

10/31/17

Wallace Fuhrman BA, CNMT, RT(R)(N)
Radiation Safety Officer
Radiation Safety Consultant for St Louis Region

Date

Damon Harbison
Chief Operating Officer – Administration
SSM Health-Cardinal Glennon Children's Hospital

10/31/17

Date

SSMHealth

FAX Cover Page

To: COLLEEN CASEY From: WALLACE FUHRMAN

Phone (recipient): _____ Phone (sender): 314-795-0891

Fax: 630-515-1078 Date: 10/31/17

No. of pages (including cover): 6

Subject line: SIR-SPHERES ADDITIONAL INFO.

IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL THE SENDER IMMEDIATELY.

THIS FAX SHOULD BE READ BY RECIPIENT ONLY.

Message:

COLLEEN,

INFORMATION YOU REQUESTED FOR SIR SPHERES AMENDMENT - CARDINAL GLENNON.

AMENDMENT # 24-32264-01
DOCKET # 030-3553
CONTROL # 600335

Wally.