SPECTRUM HEALTH
Lakeland

02/03/2021

ATTN:
Nuclear Regulatory Commission
Region III, Materials Licensing Branch
2443 Warrenville Rd., Ste. #210
Lisle, IL 60532-4352

RE: Docket Number 030.02049 Amendment to NRC License No. 21-04177-01, Spectrum Health Lakeland.

Please see the following response to the request for additional information.

Please allow for Conditional Authorization of Joel Vander Lugt, M.D. as an Authorized User. Dr. Vander Lugt will complete at least the first three hands-on patient cases under the supervision of and in the physical presence of an Authorized User who is authorized for Y-90 microspheres as Sir-Spheres. He will commit to initiating these cases within six months following the issuance of the amendment thereby allowing Dr. Vander Lugt as a conditional Authorized User upon completing the three cases within a year. Confirmatory documentation of the completion of the three patient cases will be submitted to the NRC within 60 days of when the three cases are completed. Continual training (e.g. one additional mock case prior to performing patient cases) in the use of Y-90 Sir-Spheres will be a commitment until the first three patient cases are completed.

A commitment will be made to provide training in the procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training will be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

We will meet the general requirements in 10 CFR Part 35, Subpart A, "General Information; Subpart B, "General Administrative Requirements;" Subpart C, "General Technical Requirements;" Subpart L, "Records;" and Subpart M, "Reports," except as specified in this guidance. Additionally, applicants will meet applicable requirements of 10 CFR Parts 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations;" Part 20, "Standards for Protection Against Radiation;" and Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

We will commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except when replaced by the following licensing commitments:

Procedures for Administration will be followed according to the manufacturers procedures or submitted alternative methods for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and determining if a medical even has occurred (e.g.

performing pre- and post-vial dose measurements with appropriate instrumentation, evaluating post-treatment imaging.

Written Directives will include the patient's name; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the model of spheres (e.g. TheraSphere@ or SIR-spheres@) or manufacturer; the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis."

If an administration is terminated due to stasis confirm that the record will be prepared within 24 hours after the completion of the termination of the administration and will include to the name of the individual who determined the administered dose or activity, the signature of an AU for Y-90 microspheres, and the date signed.

If the procedures must be modified due to emergent patient conditions that prevent administration in accordance with the written directive, we will confirm that the AU shall document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive will include the reason for not administering the intended dose or activity, the signature of an AU for Y-90 microspheres, and the date signed.

We will confirm that in place of 10 CFR 35.3045(a), we commit to report any event, except for an event that is caused by shunting as described in the criteria below, or as a result of patient intervention, as defined in 10 CFR 35.2 as an actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration. The criteria for event reporting is: • the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue; and o an administration of the wrong radionuclide or type of microsphere; or o an administration to the wrong individual or human research subject; or o an administration by the wrong route of administration; or o an administration by the wrong mode of treatment; or • the total dose or activity delivered 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 that prescribed; or •A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding shunting as defined in Section 6.1 when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.)

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

Sealed Source and Device Use will comply with only Y-90 microspheres for therapeutic medical uses as approved in the Sealed Source and Device Registries for TheraSphere and SIR-spheres including and required maximum activity per vial limits.

For Inventory, we will commit to follow the requirements for brachytherapy source accountability (10 CFR 35.406), receipt (10 CFR 20.1906), labeling (10 CFR 20.1904 and 10 CFR 35.69), storage (10 CFR 20.1801 and 10 CFR 35.92), and disposal to ensure accountability of Y-90 in the form of microspheres possessed under the license.

SPECTRUM HEALTH
Lakeland

For labeling, we will commit to the following when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer: • Label vials and vial radiation shields with the radioactive device (i.e. SIR-spheres, TheraSphere); and • Label syringes and syringe radiation shields with the radioactive device.

For Patient Release, we will 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

We commit to performing surveys, with an appropriate radiation detection survey instrument, all areas where the Y-90 microspheres are prepared for use or administered will occur. The survey will be conducted immediately following each preparation and administration in unrestricted areas and by the end of the day for restricted areas. We will commit to retaining records of surveys for three years, and the records will include the date of the survey, the instrument used to perform the survey, and the name of the individual who performed the survey.

For Waste Disposal, we will commit to follow the requirements of 10 CFR 35.92 and confirm that if waste is determined to contain impurities with a physical half-life of greater than 120 days that can be distinguished from the background radiation level with an appropriate survey meter that waste will be: • return the Y-90 microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or • transfer the Y-90 microspheres to an authorized recipient pursuant to requirements in 10 CFR Part 20 and Part 30

If there are any further questions, please let me know.

Sincerely,

David E. Sieffert, M.S., DABR
Medical Physicist
Radiation Safety Officer
Spectrum Health Lakeland
1234 Napier Ave.
St. Joseph, MI 49085
E-mail: david.sieffert@spectrumhealth.org
Ph. 269-985-4593