UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 1, 2023

Joel Rogers, M.S., DABR
Radiation Safety Officer
VHS Sinai-Grace Hospital, Inc.
6071 W Outer Dr.
Detroit, MI 48235

Dear Mr. Rogers:

This letter is regarding the request dated February 28, 2023, signed by Giridhar Purushotham, CEO, to amend your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-00299-04.

The U.S. NRC's guidance document applicable to the request, which I refer to below as "the guidance," is Y-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance, Rev. 10.2. This guidance is available on the U.S. NRC website at: https://www.nrc.gov/docs/ML2108/ML21089A364.pdf

Upon review of the request, I identified the following areas requiring additional or clarifying information:

1. Section 4.3, "Facility Address and Description," of the guidance states that the request should include a description of the location where the Y-90 microspheres will be used and stored.

   The request includes a diagram and description of the locations where the Y-90 microspheres will be used and stored, but the diagram and description lack adequate detail.

   Please resubmit the diagram and description of the locations where the Y-90 microspheres will be used and stored, identifying all of the following for new areas of use and storage within your licensed facility. Specifically, please provide the following:

   - dimensions/scale for the areas/rooms where radioactive material will be received, stored and used. The direction of north should be indicated.
   - describe adjacent areas/rooms to the areas where radioactive material will be received, stored and used (e.g. hallways, outside/exterior, labs, waiting room, hallway, office, etc.).
   - describe/label details such as sinks, dose calibrator, L-block, shielded cave, fume hood, material receipt area and waste storage inside the hot lab.
   - describe the availability of additional equipment used for handling and storing radiopharmaceutical therapy dosages; and
   - describe measures to secure radioactive material (e.g. describe or label locking doors, cabinets or containers, etc.)

2. Section 5.1, “Authorized Users,” identifies that acceptable training and experience includes current qualification as an Authorized User for medical use in 10 CFR §35.1000 for Y-90 microspheres.

   The request identifies that the proposed Authorized User, Richard Joyrich, M.D., is authorized to serve as an Authorized User of yttrium-90 TheraSpheres as permitted by Title 10 of the Code of Federal Regulations (10 CFR) §35.1000 on U.S. Nuclear Regulatory Commission Materials License No. 21-04127-02.

   Upon review of the referenced license, I found that this license does not specifically identify Authorized Users, but instead permits the licensee’s Radiation Safety Committee to designate Authorized Users in writing. Therefore, please submit documentation documenting that Richard Joyrich, M.D., is an Authorized User on the referenced license.

   In addition, please submit a written attestation identifying that the proposed Authorized User has satisfactorily completed the criteria described in paragraphs A and B of Section 5.1 of the guidance. The attestation may be obtained from an Authorized User who is authorized for the type of Y-90 microspheres for which the individual is seeking authorization.

3. Section 5.1, “Authorized Users,” identifies that the proposed Authorized User must have attained training in the operation of the delivery system, safety procedures, and clinical use of the type of Y-90 microspheres for which authorization is sought. Clinical use training to support unsupervised use should include at least three hands-on patient cases for each type of Y-90 microsphere requested, conducted in the physical presence of an Authorized User who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization.

   The request identifies that the proposed Authorized User, Gulcin Altinok, M.D., will participate in in three proctored cases using Y-90 TheraSpheres.

   Submit documentation demonstrating that the proposed Authorized User has completed the criteria described in paragraphs A and B of Section 5.1 of the guidance, including at least three clinical cases. Note that if the proposed Authorized User is unable to complete patient cases prior to authorization, you may submit documentation of the proposed Authorized User’s completion of mock simulated cases to allow for conditional approval.

4. Section 6.2.1, “Termination of Treatment Due to Stasis,” of the guidance identifies that the total dose or activity to the treatment site, following termination of treatment due to stasis, is the value of the total dose or activity administered when stasis occurred and the administration was terminated.

   The submitted procedures do not identify how you will determine the value of the total dose or activity administered to the treatment stie when stasis occurs.

   Please confirm that the value of the total dose or activity administered recorded will be the total dose or activity administered to the treatment site at the time that the treatment is terminated due to stasis.

5. Section 6.9, “Radiation Protection Program Changes,” of the guidance identifies that a licensee currently authorized to use Y-90 TheraSpheres in accordance with the licensing guidance must apply for and receive a license amendment in order to make program changes to conform with subsequent revisions to the guidance. You may request to incorporate a change process similar to 10 CFR §35.26. Such a change process can allow some future changes to your radiation safety programs without a license amendment provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

   - the revision is in compliance with the regulations;
   - the revision is based upon NRC’s current guidance for TheraSphere® Y-90 microspheres 35.1000 use posted on the NRC’s Medical Uses Licensee Toolkit Web site;
   - the revision has been reviewed and approved by the licensee’s RSO and licensee’s management;
   - the affected individuals are instructed on the revised program before the change is implemented;
   - the licensee will retain a record of each change for five years;
   - 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.

   The request does not include a clear commitment to establishing a change process.

   While not required, you may wish to establish a change process to make future program changes without a license amendment. Please clarify if you’d like to establish a change process. If applicable, include the applicable conditions above in your description.

In accordance with 10 CFR §2.390 of the NRC’s “Rules of Practice,” a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

To continue review of your request, please submit your response to this letter within 15 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Digitally signed by Jason M. Kelly
Date: 2023.05.01 13:43:31 -05'00'
Adobe Acrobat version: 2023.001.20143

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-01992
License No.: 21-00299-04
Control No.: 634655