From:	Weidner, Tara
To:	demetrios.Makrides@nuvancehealth.org
Cc:	Engelmann, Elizabeth
Subject:	Norwalk - NRC request for additional information
Date:	Monday, June 08, 2020 3:04:33 PM

Licensee: Norwalk Hospital
License No.: 06-06941-01
Docket No.: 03001267
Mail Control No.: 618751

Dear Mr. Makrides,

Would you please reply to this email to confirm receipt?

This is in reference to your letter dated February 17, 2020, requesting to amend NRC License No. 06-06941-01. Please note the NRC has published guidance for licensing Y-90 SIR-Spheres®. The guidance was updated in March 2020 and can be found here: https://www.nrc.gov/docs/ML2008/ML20080J208.pdf. In order to continue our review, please provide the following additional information:

1. Please confirm that you 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 the in the Microsphere Guidance.

2. Regarding the radionuclide chemical/physical form, please confirm that your request is for Resin microspheres Sirtex Model SIR-spheres® as listed in the Sealed Source and Device Registry.

3. Regarding the proposed Authorized Users (AU) conditional approval, the proposed AU should initiate the three clinical cases within six months following the license amendment and complete the clinical casework within a year following the license amendment that names the individual as an AU for Y-90 microsphere use. Please make a statement that the clinical casework will be completed within this timeframe or confirm that you will request an extension, with supporting documentation committing to performing additional training and experience (e.g. one additional mock case prior to performing patient cases) in the use of Y-90 microsphere requested until the first three patient cases are completed.

4. During the transmission of your letter the attachments were lost. Please provide the following information:

    a. A copy of Dr. Strauss' training from the manufacturer representative of the three mock simulated cases demonstrating his training in the operation of the delivery system, safety procedures, and issues encountered during administration.

    b. A copy of Dr. Strauss' board certificate.

    c. A copy of the facility diagrams referenced in your letter.

4. Please provide a copy of the training as specified in 10 CFR 35.50 regarding the Radiation Safety Officer's training specific to radiation safety, regulatory issues, and emergency procedures for Y-90 microsphere use.

6. Regarding proposed license commitment number 5, please state whether manufacturer's procedures will be used for determining shunting to non-treatment sites and determining if a medical event has occurred. If the manufacturer's procedures will not be used, please provide an alternative method.

7. Regarding proposed license commitment number 6, please commit to developing, implementing, and maintaining written procedures for microsphere accountability which include: receipt, labeling, storage, and disposal.

8. Regarding proposed license commitment number 9, please update the statement to reflect the current regulations and guidance as follows:

   In place of 10 CFR 35.3045(a), the licensee shall 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
     - an administration of the wrong radionuclide or type of microsphere; or
     - an administration to the wrong individual or human research subject; or
     - an administration by the wrong route of administration; or
     - 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.)

9. Please make a commitment that you will only yttrium-90 microspheres for therapeutic medical uses as approved in the Sealed Source and Device Registries for SIR-spheres®, including maximum activity per vial limit.

10. Section 6.8 of the microsphere guidance describes how and when surveys should be performed with regards to the Y-90 microspheres. Please describe your survey program following microsphere use and administration.

In order to continue prompt review of your application, we request that you submit your response within 30 calendar days from the date of this email. We will continue our review upon receipt of this information. Please reply to my attention at tara.weidner@nrc.gov. Please ensure that the response is signed by management and is sent in a .pdf format.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html. Please be aware that you may request that certain portions of your submittal to NRC be withheld form public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me via electronic mail at Tara.Weidner@nrc.gov.

Thank you for your cooperation.

Tara L. Weidner
Senior Health Physicist
US Nuclear Regulatory Commission