From: Tindle-Engelmann, Elizabeth
To: Blankenship, Bette
Cc: Weidner, Tara
Subject: NRC / Hartford Hospital Request for Additional Information MC 623652
Date: Friday, December 18, 2020 6:06:00 AM

Licensee: Hartford Hospital
License No.: 06-00253-04
Docket No.: 03001239
Mail Control No.: 623652

Dear Ms. Blankenship,

Would you please reply to this email to confirm receipt?

This is in reference to your letter dated November 3, 2020, requesting to amend NRC License Number 06-00253-04. Please note the NRC has published guidance for licensing Y-90 TheraSpheres®; the guidance is titled "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance". 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 make a statement 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 Yttrium-90 Microsphere Licensing Guidance.

2. The Sealed Source and Device Registry for Y-90 TheraSpheres® changed from NR-0220-D-131-S to NR-1490-D-101-S on February 3, 2020.

    a. Please confirm you are requesting Yttrium-90 glass microspheres from BWXT ITG Canada, Inc., Model TheraSphere®, as listed in Sealed Source and Device Registry NR-1490-D-101-S for the use of permanent brachytherapy using the delivery system as listed in the Sealed Source and Device Registry.

    b. Please make a statement that you will use only Y-90 TheraSpheres® for therapeutic medical uses as approved in the Sealed Source and Device Registries for TheraSpheres®, including maximum activity per vial limit.

3. In addition to the description for the nuclear medicine hot lab and the interventional radiology imaging suite, please confirm the address of use.

4. Regarding the proposed Authorized User's (AU) conditional approval, the proposed AU should initiate 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 TheraSphere® use. For the clinical casework the AU should complete at least the first three hands-on patient cases supervised in the physical presence of an AU who is authorized for Y-90 TheraSphere® use.

a. 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 in the use of Y-90 TheraSphere® until the first three patient cases are completed and that documentation of the casework will be sent to the NRC Region I Office within 60 days of completion.

b. Please make a statement that you will provide a written attestation that the individual has satisfactorily completed the requirements in section 5.1 of the NRC's Yttrium-90 Microsphere Licensing Guidance to the NRC Region I Office within 60 days of completion. Specifically, the attestation should state that the individual has satisfactorily completed the requirements in criteria A and B of section 5.1 of the NRC's Yttrium-90 Microsphere Licensing Guidance and is able to independently fulfill the radiation safety-related duties as an AU for Y-90 TheraSpheres®.

5. Please make a statement that you will follow the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; determining shunting to non-treatment sites; and determining if a medical event has occurred. Alternatively, you may submit alternative methods for calculating and documenting the dose or activity to the treatment site; determining shunting to non-treatment sites; and determining if a medical event has occurred.

6. Regarding section 1.8 Event Reporting, please update the statement to reflect the current regulations and guidance as follows:
    a. 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.)

7. Please state that if the TheraSpheres® are placed in vials, syringes, or radiation shields that are not labeled by the manufactured that you will labeled the container appropriately. Specifically, please confirm the following:

    a. Vials and vial radiation shields with the TheraSpheres® will be labeled.

    b. Syringes and syringe radiation shields with the TheraSpheres® will be labeled.

8. Please state that you will 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 will continue our review upon receipt of this information. Your reply must be a letter signed and dated. The letter may be scanned and submitted as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. Please reply within 30 calendar days from the date of this email.

If you have any questions regarding this request for additional information, please contact Elizabeth Tindle-Engelmann at 610-337-5115 or via email at Elizabeth.Tindle-Engelmann@nrc.gov.

Thank you for your cooperation.

Elizabeth Tindle-Engelmann
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