From:	Forster, Sara
To:	Bryce Caudle
Subject:	Additional Information Request for IOM Health System, LP d/b/a Lutheran Hospital of Indiana, NRC Lic. No. 13-01535-01, CN627367
Date:	Friday, September 03, 2021 1:52:00 PM

Dear Mr. Caudle:

Our office has reviewed the above-referenced licensee's July 15, 2021 request to add a Title 10 of the *Code of Federal Regulations* (CFR) Section 35.1000 yttrium-90 as TheraSphere authorization for the licensee's existing 10 CFR 35.1000 yttrium-90 as SIR-Spheres Authorized User (AU) Saad M. Ibrahim, M.D. The application omitted the referenced AU's TheraSphere-specific training and experience, as requested in NRC's Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance; April 20, 2021, Revision 10.2, pp. 5-8. Additional information is needed to complete the review, as noted below.

1. Please indicate the dates and supervising individual under which Dr. Ibrahim has completed work experience or training – under the supervision of an AU (or a manufacturer representative, through November 8, 2021) – in the use of TheraSphere, under 10 CFR 35.1000, including:

    a. Preparing and administering patient dosage. The individual does not have to be the physician who places the micro-catheter or administers patient dosage, but it is necessary that the individual have training in the administration process, including selection of activity of Y-90 microspheres to be administered to each treatment site and catheter positioning to ensure administration of the Y-90 microspheres is in accordance with the written directive; and
    b. Using administrative controls to prevent a medical event involving the use of byproduct material; and
    c. Evaluation of patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred.

2. Please indicate the dates and supervising individual under which Dr. Ibrahim has uccessfully completed training in the operation of the delivery system, safety procedures, and clinical use – under the supervision of an AU (or a manufacturer representative, through November 8, 2021) for TheraSphere, under 10 CFR 35.1000. This requirement may be satisfied by completing a training program provided by the vendor for new users or by receiving training supervised by an AU who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization. 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 AU who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization.

    However, if a proposed AU cannot complete patient cases prior to authorization; the licensee may request conditional approval with the proposed AU's completion of at

least three mock simulated cases. Mock simulated cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures and should be completed by the individual in the physical presence of a manufacturer representative or an AU who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization. Following conditional approval, the individual should complete the clinical casework described above, including case work, within a year following the license issuance or amendment that names the individual as an AU for Y-90 microsphere use. The licensee may submit documentation to the NRC requesting an extension of this timeframe. The supporting documentation should include a commitment to perform continuing T&E (e.g., one additional mock case prior to performing patient cases) in the use of the type of Y-90 microsphere requested until the first three patient cases are completed,

3. Please provide a written attestation – provided by an AU (or a manufacturer representative, through November 8, 2021) – that the individual has satisfactorily completed the requirements in criteria A and B of this section and is able to independently fulfill the radiation safety-related duties as an AU for the type of Y-90 microsphere requested.

4. The applicant must submit documentation of the above T&E for all physicians requesting authorization to use Y-90 microspheres. This documentation shall include the clinical use cases and written attestation and supervising physician T&E, if necessary. For individuals completing the patient cases following the license amendment, this documentation shall include documentation from the manufacturer representative or supervising physician of the three mock simulated cases and a commitment that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of an AU6 who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization. The documentation should commit to initiating these three cases within six months following the license issuance or amendment that names the individual as an AU for Y-90 microsphere use and complete the three cases within a year. Additionally, for applicants that have individuals completing the patient cases following the license amendment, the applicant's commitment will include submitting documentation from the manufacturer to the appropriate NRC Regional Office within 60 days of when these three patient cases have been satisfactorily completed.

Please provide additional information under a signed and dated letter. For quickest processing, you may attach it as a pdf file to an email message. Do not hesitate to let me know, should you have any questions.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
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