

From: [Gallagher, Robert](#)
To: [Momodou Dibba](#)
Subject: Request for Additional Information - Sibley Memorial Hospital
Date: Thursday, September 23, 2021 3:14:00 PM
Attachments: [image002.png](#)

License No. 08-07398-03
Docket No. 03014754
Control No. 628111

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

This refers to your letter dated July 16, 2021 in which you request the addition of two authorized users (AU) authorized for 10 CFR 35.300 and Y-90 microspheres. In order for us to continue our review the following additional information is requested:

1. Please provide copies of Board Certification for Dr. Srinivas and for Dr. Bhagat;
2. Please provide a copy of New Jersey State Radioactive Materials License No. 440570-RAD16002 listing Dr. Srinivas as an AU for 10 CFR 35.300 including parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
3. Your application includes adding authorization for both individuals to use Yttrium-90 microspheres and that supporting documentation is provided in the enclosure. The enclosure in the docket contains an NRC Form 313A (AUT) for both individuals but not information to support authorization for Y-90 microspheres. Please submit the information the information described in Section 5, "Training and Experience," in "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance. The guidance may be found at:

<https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>

Regards,

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