MidMichigan Health
UNIVERSITY OF MICHIGAN HEALTH SYSTEM

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9/30/2021

United States Nuclear Regulatory Commission
Region III, Materials Licensing
2443 Warrenvillle Road, Suite 210
Lisle, IL 60532-4352

RE: Amendment to NRC License No. 21-01549-02
Addition of Authorized User for Yttrium-90

Dear Sir/Madam:

Per the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance; April 20, 2021, Revision 10.2, we commit to the following the license amendment approving Dr. Wang as an authorized user for Y-90:

- Initiating three patient cases under the supervision of an AU who is authorized for Y-90 TheraSphere within six months of the license amendment.
- Documentation from the manufacturer will be sent within 60 days of completion of these three supervised patient cases.

Thank you for your cooperation. If you have any questions or require additional information, please contact us at radiation.safety@midmichigan.org, or by phone at (989)839-1419.

Respectfully Yours,

Victor D. Hosfeld, MS, DABR
Radiation Safety Officer, MidMichigan Health
Chief Physicist, MidMichigan Health

From: Forster, Sara
To: Pavon, Sandy
Cc: Tomczak, Tammy
Subject: FW: Additional Information to MidMichigan Health, NRC Lic. No. 21-01549-02, CN628530
Date: Thursday, September 30, 2021 11:29:25 AM
Attachments: Response Letter Amendment Wang Y90.pdf

Good morning, Sandy:

Could you please add this document to ADAMS? It is additional information to the referenced license action. Please send me the accession number and 665 form once entered.

Thank you,

Sara Forster

From: Radiation.Safety@midmichigan.org <Radiation.Safety@midmichigan.org>
Sent: Thursday, September 30, 2021 10:53 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Cc: Victor.Hosfeld@midmichigan.org
Subject: [External_Sender] RE: Additional Information Request for MidMichigan Health, NRC Lic. No. 21-01549-02, CN628530

Hello Sara,

Please see the refer to the attached letter for the additional information requested.

If you have any further questions or need any additional information please let us know.

Thank you,

Cameron Hodges
Radiation Safety Coordinator
Office of Radiation Safety
(989)839-1419
cameron.hodges@midmichigan.org

From: Forster, Sara [mailto:Sara.Forster@nrc.gov]
Sent: Thursday, September 23, 2021 9:20 AM
To: Radiation Safety
Subject: Additional Information Request for MidMichigan Health, NRC Lic. No. 21-01549-02, CN628530

Dear Mr. Hosfeld:

Our office has reviewed the above-referenced licensee's September 8, 2021 request to add a Title 10 of the *Code of Federal Regulations* (CFR) Section 35.1000 yttrium-90 as TheraSphere Authorized User (AU) Shengfu Wang, 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. Wang has successfully 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. Only one such case, completed on June 21, 2016, appears to be included with the request.

   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.

2. 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.

3. 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 AU 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. If mock cases are being used to support the request, or a combination of mock cases and the single actual case, no commitments to timely complete the additional patient cases appear to have been included with the request. Those commitments would be needed, to add Dr. Wang as an AU, with the documentation included in the September 8, 2021 letter.

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. A response is requested within the next 21 days (on or prior to October 14, 2021). Do not hesitate to let me know, should you have any questions.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
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immediate reply.