From: <u>Gryglak, Magdalena</u>
To: <u>James Hatten</u>

Cc: Kelli Goodwin; Michael Moldenhauer; Matthew Shebel

Subject: RE: Request to authorize Dr. Kim for use of 10 CFR 35.1000 (Y-90) material

**Date:** Monday, July 12, 2021 7:05:00 PM

Thank you for the clarification.

Because the documentation is not specific enough and I do not have prior knowledge of Dr. Kim's experience when he was authorized for use of 10 CFR 35.200 material, please provide the following:

## Please provide:

- Dr. Kim's original Board Certificate (with "AU ELIGIBLE" designation, if applicable) in Diagnostic Radiology (I verified online Dr. Kim is ABR certified in Diagnostic Radiology),
- 2. Dr. Kim's (a) Board Certificate in Interventional radiology, if applicable (if Dr. Kim received the Board certificate), or (b) a written letter providing the dates of Dr. Kim's Vascular and Interventional Radiology fellowship at the University of Chicago Medical Center signed by RSO (Mr. Hatten)/AU/University of Chicago Medical Center Program director or Authorized User (AU).
- documentation of Dr. Kim's training and experience in Interventional Radiology including administering Y-90 SIR-Sphere material under supervision of an AU (NAME) at the La Porte Hospital on DATES/RANGE signed by an AU.
- 4. If applicable (based on 9/26/18 letter demonstrating that Dr. Kim performed 3 in vivo/ clinical cases of Y-90 administration and additional experience at the La Porte Hospital), please provide an attestation signed by AU for Y-90 SirSpheres attesting that "Dr. Kim has satisfactorily completed the training and experience requirements in Section 5.1.A and 5.1.B of the NRC guidance "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance," Revision 10.2 and is able to independently fulfill the radiation safety-related duties as an Authorized User for the use of Y-90 SIR-Spheres.

Please note items 3 and 4 can be combined in one letter signed by the same supervising AU.

Please let me know if you have any questions.

Please provide the information by July 30, 2021.

Thank you

Magdalena

From: James Hatten < jhatten@sahci.com>

**Sent:** Monday, July 12, 2021 3:38 PM

To: Gryglak, Magdalena < Magdalena. Gryglak@nrc.gov>

**Cc:** Kelli Goodwin <sahci@sahci.com>; James Hatten <jhatten@sahci.com>; Michael Moldenhauer

<m.moldenhauer@nwhealthin.com>; Matthew Shebel <m.shebel@nwhealthin.com>

**Subject:** [External\_Sender] RE: Request to authorize Dr. Kim for use of 10 CFR 35.1000 (Y-90)

material

## Magdalena R. Gryglak

- 1. Yes we are using his 300.200 experience, SIRTEX training, and his Interventional Radiology Experience. He has been working under the supervision of the SIRTEX AU since his training in 2018.
- 2. A better copy of the IR certificate is attached.

I confirmed below that the IR board certificate requires at least a one year fellowship. Dr Kim has more than three years of experience at this hospital.

IR Candidates will be required to complete one year of post-fellowship training practice experience in IR (minimum 33 percent of a 1.0 FTE) to be eligible for the IR/DR Certifying exam

Let me know what else you need to process our request.

Thanks you for your support.

Jim Hatten LaPorte RSO

**From:** Gryglak, Magdalena < <u>Magdalena.Gryglak@nrc.gov</u>>

**Sent:** Friday, July 9, 2021 5:20 PM **To:** James Hatten < <u>ihatten@sahci.com</u>>

Subject: Request to authorize Dr. Kim for use of 10 CFR 35.1000 (Y-90) material

Good afternoon Mr. Hatten,

I have reviewed your request dated 6/8/21 to authorize Dr. Kim for use of Y-90 SirSpheres.

- 1. Please address/clarify Dr. Kim's training and experience in the NRC guidance for Y-90 (see attached), Section 5.1.A.3.i (are you taking credit for Dr. Kim's experience in diagnostic radiology as an AU for 10 CFR 35.200 material?)
- 2. Please resubmit Dr. Kim's certificate in Vascular and Interventional Radiology dated June 30, 2013 (the certificate is not legible). Does the certificate have dates demonstrating a year of experience?

Thank you

Magdalena R. Gryglak Health Physicist U.S. NRC Region III