

Request for Additional Information:

- 1) To authorize Dr. James Fontanesi as an Authorized User for Gamma Knife Icon, please provide the following:

- A) Letter attesting that James Fontanessi, M.D. attended the Gamma Knife Icon training on 6/5-7/19 and that the Gamma Knife training included hands-on device operation, safety procedures, and clinical use which included preparing treatment plans and calculating treatment doses and times for the Icon gamma knife stereotactic radiosurgery unit. The training also included the differences in the device operation, safety procedures and clinical use of the Icon and the Type C.

The letter can be signed by one of the trainers at the Cleveland Clinic or yourself attesting to the above.

- 2) To authorize L. Benedetti, M.S. as an Authorized Medical Physicist for Gamma Knife Icon, please provide the following:

- A) Since Ms. Benedetti's board certification is not recognized by the NRC (Board Certification issued in 1995), please provide Ms. Benedetti's training and experience in accordance with 10 CFR 35.51 (b)(1) and (2) or another license where Ms. Benedetti is authorized for use of a stereotactic radiosurgery unit. Please note that the training and experience can be with any gamma stereotactic radiosurgery unit.

- B) Documentation that L. Benedetti M.S. attended the Gamma Knife Icon training on 12/3-7/19 and the Gamma Knife training included hands-on device operation, safety procedures, and clinical use and the operation of a treatment planning system for the Icon.

The training may be also provided by an AMP authorized for use of the Icon and attesting that the training included hands-on device operation, safety procedures, and clinical use and the operation of a treatment planning system for the Icon.

The documentation can be signed by one of the trainers at the Cleveland Clinic or yourself attesting to the above.

- C) Written attestation from a preceptor Icon AMP that: 1) Ms. Benedetti has satisfactorily completed the hands-on device operation, safety procedures, and clinical use and the operation of a treatment planning system for the Icon, and 2) Ms. Benedetti is able to independently fulfill the radiation safety-related duties as an AMP for the Icon unit.

- 3) To authorize L. Benedetti, M.S. as an Associate Radiation Officer for Gamma Knife Icon: (Ms. Benedetti can be approved as the ARSO if she is qualified to be the AMP on the license or if the training and experience is provided in accordance with 10 CFR 35.50 (b)(1) and (2)), please provide the following:

- A) Documentation of training and experience in accordance with 10 CFR 35.50 (b)(1) and (2), if applicable.

- B) Documentation that Ms. Benedetti received training in the radiation safety, regulatory issues and emergency procedures for the use of Icon during the vendor training or other training (Date and Location).
- C) Documentation that Ms. Benedetti completed (Date and Location) or will complete supplemental hands on radiation safety and emergency procedures training on operational Icon unit before first use of the unit for patient treatment.
- D) Written attestation from a preceptor Icon AMP/RSO that: 1) Ms. Benedetti has satisfactorily completed the radiation safety, regulatory issues and emergency procedures for the use of Icon, 2) Ms. Benedetti completed or will complete supplemental hands on radiation safety and emergency procedures training on operational Icon unit before first use of the unit for patient treatment; and 3) Ms. Benedetti is able to independently fulfill the radiation safety-related duties as an Radiation Safety Officer or an Associate Safety Officer for the medical use of the Icon unit.

Gryglak, Magdalena

From: Gryglak, Magdalena
Sent: Monday, July 01, 2019 9:33 AM
To: 'Maitz, Ann'
Subject: Request to name AU, AMP and ARSO, NRC License no. 21-01333-02, Beaumont Health System, CN 612450
Attachments: Request for Additional Information.docx

Good morning Ms. Maitz,

I have reviewed your request to add a new Authorized User and Authorized Medical Physicist/Associate Radiation Safety Officer to the subject NRC license.

The attached document contains a list of additional information needed to proceed with the request.

Please let me know if you have any questions.

Thank you

Magdalena R. Gryglak
US NRC Region III
630-829-9875