

**Forster, Sara**

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**From:** Forster, Sara  
**Sent:** Tuesday, June 20, 2017 11:07 AM  
**To:** 'robert.gilliam@hcamidwest.com'  
**Subject:** Additional Information request re Research Medical Center - Gamma Knife Center, NRC Lic. No. 24-17998-02, CN599625

Dear Mr. Gilliam:

We have reviewed your May 15, 2017 letter (ML17138A268) requesting an authorization for the medical use of a Leksell Gamma Knife® Icon™ unit, including to remove your authorization for the Elekta Leksell Gamma System Model C device and to add an Authorized Medical Physicist and an Authorized User to your license. As we discussed via telephone earlier today (June 20, 2017), additional information is needed to complete our review. In addition to details surrounding removal of sources associated with the Model C GSR unit, we have noted that there was no discussion of possession limit changes requested or confirmation that commitments contained in your January and March 2017 letters would be followed. Finally, we did not see a confirmation that the ICON device will be used under physical conditions as described in the applicable sealed source & device registry certificate. Accordingly, to remove the Model C device (including any associated research & development authorizations) and to update the authorized use for the ICON device to include medical use, please provide the following information:

1. To remove the authorization for cobalt-60 permitted by 10 CFR 35.600, please provide additional items noted below:

**A. Leak Tests and/or Survey information:**

- i. Confirmation that the licensee has never possessed any leaking sources under the license
- ii. Most recent leak tests for sealed sources associated with the removed Elekta Leksell Gamma System Model C

**B. Final Disposition of Model C Information:**

- i. Date the device and sources were removed from the licensed facilities
- ii. Date on which device and sources were received by a duly authorized recipient (i.e. manufacturer/distributor or specifically licensed facility)
- iii. Letter from authorized recipient confirming receipt of removed sources/device

2. To revise the ICON device authorization listed on your license, please provide the following:

- A. possession limit is as listed in your January 3, 2017 letter (ML17004A134); and
- B. use is limited to medical use as permitted in 10 CFR 35.1000, as listed in your January 3, 2017 letter (ML17004A134)
- C. the licensee will adhere to commitments contained in your January and March 2017 letters, as applicable.

3. To remove Authorized User Jay S. Robinow, M.D., from your license, please confirm such removal.

4. To list David T. Shaeffer, M.D. as an Authorized User, please provide specific documentation of training and experience applicable to the medical use of the ICON device.

5. To add an additional Authorized User, please provide her name and documentation showing that she is qualified in the use of the ICON device. If she is listed on another NRC or Agreement State license, please provide the license number for that license. If she is listed on a permit under a Broadscope NRC or Agreement State license, please provide a copy of that permit OR a letter from that licensee's Radiation Safety Officer and/or Radiation Safety Committee chairperson confirming her authorization for use of an ICON device.
6. Concerning use of the ICON, please confirm that the device will be used under physical conditions as described in the applicable sealed source & device registry certificate.

As discussed, to facilitate issuing this license by Friday, June 23, 2017, please submit additional information on or before 10:00 am on Friday, June 23, 2017. Additional guidance may be found in NUREG 1556, Vol. 9, rev. 2, "Program Program-Specific Guidance about Medical Use Licenses," which may be found at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2>

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Any response must be submitted under a signed and dated cover letter. Do not hesitate to call me with any questions you may have, or if you will need additional time to complete your response.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer  
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