From: Elliott, Robin
To: Arthur.lemay@ynhh.org
Cc: Bohan, Michael
Subject: Request for additional information for Amendment to License No. 06-00819-03, CN 594716
Date: Friday, June 02, 2017 1:40:00 PM

License No.: 06-00819-03
Docket No: 03001244
Control No: 594716

Dear Mr. Lemay:

This refers to your request to amend your license by updating the existing Leksell Gamma Knife Perfexion™ to an Icon™ gamma stereotatic radiosurgery (GSR) unit, dated May 3, 2017. Leksell Gamma Knife Perfexion™ and Leskell Gamma Knife Icon™ Licensing Guidance dated May 25, 2016, provides guidance to licensees relative to requirements for these units. https://www.nrc.gov/docs/ML1610/ML16109A208.pdf In order to continue our review of your request, the following additional information is needed:

1. Identify radionuclide, form, possession limit and purpose of use.
2. Confirm that authorized users, and authorized medical physicists approved by the Radiation Safety Committee will meet training and experience criteria described in the current version of the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon Licensing Guidance under the sections entitled "For the Icon™ unit" for each type of user. Please note that this requires hands-on device operation including treatment planning for all currently approved Perfexion users. .
3. Confirm that the Radiation Safety Officer will complete supplemental hands-on radiation safety and emergency procedures.
4. Confirm that the physical conditions of the use of the Icon™ will be as described in the Sealed Source Device (SS&D) certificate or that you will perform your own engineering and radiation safety evaluation addressing the differences.
5. Confirm that authorization for possession and use of the CBCT imaging system will be obtained from the applicable state agency prior to operation.
6. Indicated whether you request flexibility to allow future changes to the radiation safety program provided that the change process requires the following conditions to be met:
    a. The revision is in compliance with the regulations; and
    b. The revision is based upon NRC's current guidance for the Icon gamma stereotactic radiosurgery unit 35.1000 use posted on the NRC Medical Uses Licensee Toolkit; and
    c. The revision has been reviewed and approved by your RSO and management; and
    d. The affected individuals are instructed on the revised program before the change is implemented; and
    e. You will retain a record of each change for 5 years; and
    f. The record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of your management that reviewed and approved the change.
7. Confirm that you will implement the changes described in your letter dated April 18, 2017, [ML17117A641] to your 10 CFR Part 37 program prior to operation of the Icon™ unit.

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted

as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your amendment request.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Regards,

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