From: Sandra Gabriel
To: msheetz@pitt.edu
Date: Mon, Aug 20, 2007 4:54 PM
Subject: Additional questions for clinical use of Perfexion gamma knife, mail control 140839

Licensee: University of Pittsburgh
License No.: 37-00245-09
Docket No.: 03029418
Mail Control No.: 140839

To: Mike Sheetz, Radiation Safety Officer

An initial list of questions related to clinical use licensing of your Perfexion gamma knife unit was presented in the second part of an e-mail message dated August 4, 2007, numbered as items a) though h). Please add to that list the following 4 items:

i) Semi-annual spot-check to confirm that each sector moves correctly to each position:
Please provide a copy of the spot-check procedure to be used by the vendor to confirm that each sector moves correctly to each position. In a meeting with Elekta personnel last week, we learned that they were in the process of writing this procedure and saw a demonstration of the planned procedure.

j) Monthly spot-check of on-off error (e.g., timer end effect):
Please specify the collimator aperture size to be used for this test. [Our understanding is that it is possible the design of the Perfexion's collimation system may result in different on-off errors for different aperture sizes, becuse the distance traveled by the sector drive unit from the "off" position to the 16 mm apertures is longer than the distance from the "off" position to the 8 mm or 4 mm apertures.]

k) Frequency of performing Focus Precision Check:
Your submitted "Daily Quality Assurance Procedures" include the Focus Precision Check using the Elekta QA tool. As we discussed by telephone, you have the option to perform this test as part of your monthly spot-check rather than as a daily check. The Elekta Instructions for Use (IFU) state that the Focus Precision Check is required to be performed once a month, or when the frame adapter or the QA tool may have been damaged, and the IFU recommends twice monthly performance. If you wish, you may inform *us that the Focus Precision Check will be removed from your* "Daily Quality Assurance Procedures" and added to your "Monthly Spot Check Procedure."

l) Postings on treatment room door:
Item 9.E.3. attached to your letter dated July 16, 2007 stated that the *entrance door to the treatment room* is posted with a "Caution High Radiation Area" sign. Please confirm that it is also posted with a "Caution Radioactive Materials" sign, as required by 10 CFR 20.1902(e).

Please provide the responses to the original 8 items, as well as the 4 listed above, under management signature within 30 days. You may mail, FedEx, or fax your signed response to my attention at Region I, referencing mail control 140839.

Please send a return e-mail to confirm receipt of this message.

Thank you for your continued cooperation. If you have any questions, please contact me by e-mail or telephone. Please note that *I will be away beginning August 31 and returning on September 10.*

Sandy Gabriel, Ph.D.
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Medical Branch
NRC Region I
610-337-5182

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Created By: SLG2@nrc.gov

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Expiration Date:	None
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