

MidMichigan
Medical Center
Midland

Gamma Knife Department
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To BRANCH CHIEF, MATERIALS LICENSING
U.S. N.R.C., REGION III
Fax# 630 - 515 - 1078

Date & Time 10.15.07 4:30PM fax

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From: Gamma Knife Department
MidMichigan Medical Center

URGENT REQUEST

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MidMichigan
Medical Center
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October 15, 2007

Branch Chief
Materials Licensing
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Dear Branch Chief,

MidMichigan Medical Center, Midland, Michigan, license # 21-01549-02, respectfully requests permission for Rajnikant Mehta, M.D. and Ramesh Vedula, M.D. to work as authorized users for the Leksell Gamma Knife Perfexion™ Stereotactic Radiosurgery Unit. This permission is **needed by October 24, 2007**, when we have two patients pending treatment. Due to unavailability of our other radiation oncologist, Rajesh Kotecha, M.D., the patients will otherwise have to wait another two and a half weeks for treatment.

Per the requirements of the "Leksell Gamma Knife® Perfexion™ - Licensing Guidance" dated July 16, 2007 :

1. Both Rajnikant Mehta, M.D and Ramesh Vedula, M.D :are currently listed on the license as authorized users for 35.600 medical use of the Leksell Gamma System radiation therapy unit.
2. Dr. Mehta received training in device operation of the Perfexion™ on October 4th, 2007 under Larry Langrill, Licensee RSO. On October 8th and 9th, 2007, both Drs. Mehta and Vedula completed training in device operation under Karen Claeys, Elekta consultant physicist and Tracy Miller, Elekta service engineer.
3. Both Drs. Mehta and Vedula completed training in emergency and safety procedures for the Perfexion™ on October 8, 2007, under Karen Claeys, Elekta consultant physicist.

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4. Dr. Mehta trained in clinical use for the Perfexion™ on October 8 - 12, 2007. Dr. Vedula trained on October 8 - 10 and 12, 2007. This included involvement in image registration, treatment planning, plan approval and export, and delivery of Perfexion™ treatments for 10 patients for each physician. A total of 14 patients were treated during this startup week of the Perfexion™ unit. This training was under Susan Lohman, Elekta treatment planning specialist, Karen Claeys, Elekta consultant physicist, and Rajesh Kotecha, Licensee Perfexion™ authorized user.

5. Both Drs. Mehta and Vedula reviewed, on October 12, 2007, the differences in device design, operation, safety procedures and clinical use of the Perfexion™ and the previously installed Leksell gamma stereotactic radiosurgery unit. This review was under Larry Langrill, Licensee RSO and Karen Claeys, Elekta consultant physicist.

For further information or questions, please contact me directly at 517-839-3450 or at fax number 989-839-1347.

Sincerely,

A handwritten signature in black ink, appearing to read "L. Langrill", with a stylized flourish at the end.

Larry Langrill, RSO
Perfexion AMP
MidMichigan Medical Center
4005 Orchard Dr.
Midland, MI 48670