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Research Conduct and Compliance

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Randy P. Juhl, PhD
Vice Chancellor

K-8

September 17, 2007

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Attention: Sandy Gabriel, PhD

Re: Amendment Request to License No. 37-00245-09
Control No. 140839

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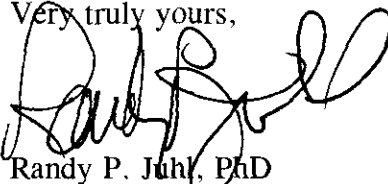
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Dear Dr. Gabriel:

This letter provides the additional information previously requested for clinical use of the LGK Perfexion.

Attached is documentation of Perfexion training received by two of our Authorized Users (Drs. J. Flickinger and Y. Arai). Also attached is a procedure (with sample data) provide by Elekta for their semi-annual sector position verification test.

If you have any questions or require additional information, please contact Michael Sheetz.

Very truly yours,

Randy P. Juhl, PhD

Attachments

140839

NMSS/RGN1 MATERIALS-002

FAX RECEIVED 9/17/2007

Leksell Gamma Knife PERFEXION training for authorized users
(radiation oncologists) at the University of Pittsburgh Medical Center

1st part –Introduction of the Leksell Gamma Knife PERFEXION 1.5 h

Radiation oncologist	Date of the training	Trainer
Flickinger John, M.D. <i>4/17/06 JF</i>	September 7, 2007	Novotny Josef, Ph.D. <i>JG</i>

Power Point presentation plus video covered following topics

Leksell Gamma Knife PERFEXION – Overview

- Technical overview
- Parts and configuration
- Features
- Benefits
- Differences in the device operation, safety procedures, and clinical use

Leksell GammaPlan PFX – Overview

- Technical overview
- Features
- Benefits
- Differences in the software operation

Leksell Gamma Knife PERFEXION – Alarms and Emergency Procedures

- Emergency alarm, System alarm
- Treatment pause sequence by pressing the PAUSE button
- Emergency Stop sequence and Emergency Exit sequence
- Manual pull-out of the couch
- Closing the shielding doors manually
- Closing the radiation sectors manually

2nd part – hands-on the new treatment planning system

2.5 h

Radiation oncologist	Date of the training	Trainer
Flickinger John, M.D. <i>Jc</i>	September 14, 2007	Novotny Josef, Ph.D. <i>Jc</i>

Hands-on the new treatment planning system included

Leksell GammaPlan PFX – Hands-on

- Demonstration of new features and differences in the Leksell GammaPlan PFX
- Treatment planning for multiple targets in the Leksell GammaPlan PFX
- Treatment planning for five different clinical cases

3rd part – hands-on the Leksell Gamma Knife PERFEXION

2.0 h

Radiation oncologist	Date of the training	Trainer
Flickinger John, M.D. <i>Jc</i>	September 17, 2007	Novotny Josef, Ph.D. <i>Jc</i>

Hands-on the Leksell Gamma Knife PERFEXION included

Leksell Gamma Knife PERFEXION treatment procedure – Hands-on

- Demonstration of standard PERFEXION treatment
- Demonstration of PERFEXION clearance check

Leksell Gamma Knife PERFEXION Alarms and emergency procedures – Hands-on

- Emergency alarm, System alarm
- Treatment pause sequence by pressing the PAUSE button
- Emergency Stop sequence and Emergency Exit sequence
- Manual pull-out of the couch
- Closing the shielding doors manually
- Closing the radiation sectors manually

Leksell Gamma Knife PERFEXION training for authorized users
(radiation oncologists) at the University of Pittsburgh Medical Center

1st part –Introduction of the Leksell Gamma Knife PERFEXION 1.5 h

Radiation oncologist	Date of the training	Trainer
Arai Yoshio, M.D. <i>W. Arai</i> <i>9/4/07</i>	September 4, 2007	Novotny Josef, Ph.D. <i>J. Novotny</i>

Power Point presentation plus video covered following topics

Leksell Gamma Knife PERFEXION – Overview

- Technical overview
- Parts and configuration
- Features
- Benefits
- Differences in the device operation, safety procedures, and clinical use

Leksell GammaPlan PFX – Overview

- Technical overview
- Features
- Benefits
- Differences in the software operation

Leksell Gamma Knife PERFEXION – Alarms and Emergency Procedures

- Emergency alarm, System alarm
- Treatment pause sequence by pressing the PAUSE button
- Emergency Stop sequence and Emergency Exit sequence
- Manual pull-out of the couch
- Closing the shielding doors manually
- Closing the radiation sectors manually

2nd part – hands-on the new treatment planning system

2.5 h

Radiation oncologist	Date of the training	Trainer
Arai Yoshio, M.D. <i>AY</i>	September 12, 2007	Novotny Josef, Ph.D. <i>JS</i>

Hands-on the new treatment planning system included

Leksell GammaPlan PFX – Hands-on

- Demonstration of new features and differences in the Leksell GammaPlan PFX
- Treatment planning for multiple targets in the Leksell GammaPlan PFX
- Treatment planning for five different clinical cases

3rd part – hands-on the Leksell Gamma Knife PERFEXION

2.0 h

Radiation oncologist	Date of the training	Trainer
Arai Yoshio, M.D. <i>AY</i>	September 17, 2007	Novotny Josef, Ph.D. <i>JS</i>

Hands-on the Leksell Gamma Knife PERFEXION included

Leksell Gamma Knife PERFEXION treatment procedure – Hands-on

- Demonstration of standard PERFEXION treatment
- Demonstration of PERFEXION clearance check

Leksell Gamma Knife PERFEXION Alarms and emergency procedures – Hands-on

- Emergency alarm, System alarm
- Treatment pause sequence by pressing the PAUSE button
- Emergency Stop sequence and Emergency Exit sequence
- Manual pull-out of the couch
- Closing the shielding doors manually
- Closing the radiation sectors manually

Sector position verification test

Measure the distance from the loading position ring to the inside of the sector emergency pull handle using a tape ruler, caliper or similar. The encoder data are collected using the Service tool and Free PPS movement.

Position 8 mm	1	2	3	4	5	6	7	8
Measured at installation	140	139	139	139	139	139	140	139
Measured during test	140	139	139	139	139	139	140	139

Encoder								
Values in configuration	11.220	11.274	11.197	11.244	11.249	11.295	11.271	11.278
Actual values	11.209	11.264	11.187	11.235	11.241	11.291	11.265	11.275

Result								
Measured difference	0	0	0	0	0	0	0	0
Encoder difference	0.011	0.010	0.010	0.009	0.008	0.004	0.006	0.003
Average difference	0.008							

Position OFF	1	2	3	4	5	6	7	8
Measured at installation	125	124	124	124	125	125	125	125
Measured during test	125	124	124	124	125	125	125	125

Encoder								
Values in configuration	25.907	25.970	25.900	25.950	25.950	26.000	25.970	25.970
Actual values	25.907	25.966	25.894	25.942	25.945	25.994	25.968	25.973

Result								
Measured difference	0	0	0	0	0	0	0	0
Encoder difference	0.000	0.004	0.006	0.008	0.005	0.006	0.002	-0.003
Average difference	0.006							

Position 4 mm	1	2	3	4	5	6	7	8
Measured at installation	111	110	110	110	110	110	110	110
Measured during test	111	110	110	110	110	110	110	110

Encoder								
Values in configuration	40.520	40.574	40.497	40.544	40.549	40.595	40.571	40.578
Actual values	40.507	40.571	40.490	40.535	40.545	40.590	40.570	40.585

Result								
Measured difference	0	0	0	0	0	0	0	0
Encoder difference	0.013	0.003	0.007	0.009	0.004	0.005	0.001	-0.007
Average difference	0.004							

Position 16 mm	1	2	3	4	5	6	7	8
Measured at installation	81	81	81	81	81	81	81	81
Measured during test	81	81	81	81	81	81	81	81

Encoder								
Values in configuration	69.920	69.974	69.897	69.944	69.949	69.995	69.971	69.978
Actual values	69.909	69.969	69.890	69.934	69.946	69.990	69.968	69.990

Result								
Measured difference	0	0	0	0	0	0	0	0
Encoder difference	0.011	0.005	0.007	0.010	0.003	0.005	0.003	-0.012
Average difference	0.004							