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Research Conduct and Compliance

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Randy P. Juhl, PhD
Vice Chancellor

August 6, 2007

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

K-8
MS-16

RECEIVED
REGION I
2007 AUG -7 AM 10:19

Attention: Sandy Gabriel, PhD

Re: Amendment Request to License No. 37-00245-09 *03029418*
Control No. 140865

Dear Dr. Gabriel:

This letter provides the additional information requested in your email dated August 4, 2007 to Michael Sheetz for issuing a license amendment for the possession and testing of the LGK Perfexion.

I have reviewed and concur with the information provided in the letter from Michael Sheetz, dated July 27, 2007, which submitted a revised source loading schedule and information requested in the NRC Leksell Gamma Knife Perfexion - Licensing Guidance Document.

Attached are the course outlines for the Elekta Perfexion training courses attended by our Authorized Medical Physicists. This training included instruction on the differences between the Perfexion and the other Elekta gamma knife units.

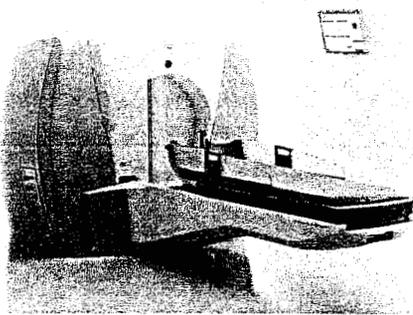
If you have any questions or require additional information, please contact Michael Sheetz.

Sincerely,

Randy P. Juhl
Randy P. Juhl, PhD

Attachments

140865
NMSS/RGNY MATERIALS-002



Leksell Gamma Knife® Perfexion™ System Start Training,

Stockholm, Sweden,
January 18 – 19, 2007

Program

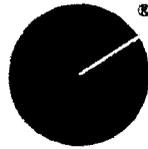
Arrival and pick up at airport January 17, according to schedule, for transport to Scandic Park Hotel, Stockholm.

Thursday, January 18

08:30	Welcome		Tomas Puusepp
08.40-09:45am	Leksell Gamma Knife Perfexion - Overview <ul style="list-style-type: none"> • Technical overview • Part and configuration • Features • Benefits 		Per Nylund
09:45-10:00am	<i>coffee</i>		
10:00-11:00am	Leksell GammaPlan PFX - Overview		Vincent Denot
11:00-12:00am	Group A Demonstration of Perfexion	Group B Sales Information	Per Nylund/Pär Nordström
12:00-01:00pm	<i>In-house Lunch</i>		
1:00-2:00pm	Group B Demonstration of Perfexion	Group A Sales Information	Per Nylund/ Pär Nordström
2:00-2:30pm	Dose planning at L' Hopital La Timone		Jean Régis, M.D.
2:30-2:45pm	<i>coffee</i>		
2:45-3:15pm	Physics - Overview		Jonas Johansson
3:15-5:00pm	Leksell GammaPlan Hands-on		Vincent Denot
7.30 pm	<i>Welcome Dinner at Restaurant Gondolen</i> <i>(Taxi pick-up at the hotel at 7.10pm)</i>		

Friday, January 19

08:30-09:30am	Leksell Gamma Knife Perfexion in clinical use		Jean Régis, M.D.
	<ul style="list-style-type: none"> • Frame placement for Perfexion treatment • Treatment planning for Perfexion • Do's and don'ts for Perfexion 		
09:30-10:30am	Physics in depth (Physicists)	Hands-on LGP (Neurosurgeons)	Håkan Nordström/ Vincent Denot
	<ul style="list-style-type: none"> • Dose calculation • System calculation 		
10:30-10:45am	<i>coffee</i>		
10:45-12:00am	Group A	Group B	Vincent Denot/ Per Nylund
	Leksell GammaPlan Hands-on	Leksell Gamma Knife Perfexion Hands-on	
12:00-01:00pm	<i>In-house Lunch</i>		
1:00-2:15pm	Group B	Group A	Per Nylund/ Vincent Denot
	Leksell GammaPlan Hands-on	Leksell Gamma Knife Perfexion Hands-on	
2:15-2:30pm	<i>coffee</i>		
2:30-3:00pm	Panel discussion – Experiences Do's and don'ts		Thomas Kraepelien/ Per Nylund/ Josef Novotny Jr.
3:00-3.30pm	Education & Training		Eva Palm
	<ul style="list-style-type: none"> • New LGK Introductory course outline • System Starts 		
3:30-4:00pm	Summary & Evaluation		Per Nylund
	<i>End of Course.</i>		
Faculty from C.H.U. La Timone, Marseille, France:	Jean Régis, M.D.		
Faculty from Elekta:	Eva Palm, Director Education & Training		
	Håkan Nordström, Physicist, Research & Development		
	Jonas Johansson, Physicist, Research & Development		
	Pär Nordström, Marketing Director, Europe and AFLAME		
	Per Nylund, Senior Product Manager, Leksell Gamma Knife		
	Thomas Kraepelien, Physicist, Research & Development		
	Tomas Puusepp, President and CEO		
	Vincent Denot, Product Manager Leksell GammaPlan		



ELEKTA
Leksell Gamma Knife® Perfexion™
Technical Training
May 29 – June 1, 2007

Tuesday, May 29

08.45	<i>Pick up in the hotel lobby</i>	
09.00-09.10	Welcome and Introduction to the Program	Liselotte Eriksson
09.10-10.00	Historical Presentation of Elekta	Dan Leksell
10.00-10.15	<i>Coffee/Tea</i>	
10.15 -11.00	Technical Presentation of Perfexion® - Features and benefits	Per Nylund
11.00-12.00	Stereotaxy for Gamma Knife Surgery	Robert Åslund
12.00-13.00	<i>Lunch</i>	
13.00-14.00	Demonstration of Perfexion®	Peter Fröberg
14.00-15.00	Physics applicable to Leksell Gamma Knife	Per Kjäll
15.00-15.15	<i>Coffee/Tea</i>	
15.15-16.00	Intro to Leksell Gamma Plan – basic workflow	Vincent Denot
16.00-17.00	Treatment according to plan	Peter Fröberg

Wednesday, May 30

09.00-11.00	Hands-on Leksell GammaPlan PFX and Perfexion <ul style="list-style-type: none">• Treatment Planning• Treatment workflow	Thomas Kraepelien
10.15-10.30	<i>Coffee/Tea</i>	
11.00-12.00	Physics – Dose calculation	Håkan Nordström
12.00-13.00	<i>Lunch</i>	
13.00-16.00	Hands-on Leksell GammaPlan PFX and Perfexion <ul style="list-style-type: none">• Treatment Planning• Treatment workflow	Thomas Kraepelien
15.00-15.15	<i>Coffee/Tea</i>	
16.00-17.00	Gamma Knife surgery – Clinical evidence and utilization	Sören Johansson
19.00	<i>Course dinner with faculty and Elekta Staff</i>	



Thursday, May 31

09.00-10.30	Technical description of Perfexion® Hands-on <ul style="list-style-type: none">• Radiation Unit• Patient Positioning system• Control System	Peter Fröberg
10.30-11.00	<i>Coffee/Tea</i>	
11.00-12.00	Hands-on Leksell GammaPlan	Thomas Kraepelien
12.00-13.00	<i>Lunch</i>	
13.00-15.00	Hands-on Leksell GammaPlan	Thomas Kraepelien
15.00-15.15	<i>Coffee/Tea</i>	
15.15-16.15	Hands-on Perfexion® <ul style="list-style-type: none">• Clearance Procedures• Emergency Procedures	Thomas Kraepelien
16.15-17.00	Current Regulatory Status and NRC applications	Peter Löwendahl, Anders Skoglund

Friday, June 1

09.00-10.00	Meet with Engineering team	Johannes Morelius, Per Carlsson
10.00-10.15	<i>Coffee/Tea</i>	
10.15-11.00	Lecture on Calibration and Practical Physics	Jonas Johansson
11.00-12.00	Hands-on Leksell GammaPlan – TPSADMIN	Thomas Kraepelien
12.00-13.00	<i>Lunch</i>	
13.00-15.00	Hands-on Leksell GammaPlan and Perfexion®	Thomas Kraepelien
15.00-15.15	<i>Coffee/Tea</i>	
15.15-16.00	Hands-on continued	Thomas Kraepelien
16.00	Evaluation and handing out of certificates	

Faculty

Dan Leksell, M.D., Vice Executive President and Clinical Director
Anders Skoglund, Manager Regulatory Affairs
Håkan Nordström, Physicist, Research & Development
Johannes Morelius, Project Manager, Leksell Gamma Knife, Research & Development
Jonas Johansson, Physicist, Research & Development
Liselotte Eriksson, Program Manager Training & System Starts, Education & Training
Per Carlsson, Principle Systems Engineer Leksell Gamma Knife Perfexion
Per Kjäll, Senior Physicist, Research & Development
Per Nylund, Senior Product Manager Leksell Gamma Knife
Peter Fröberg, Product manager Leksell Gamma Knife
Peter Löwendahl, Director Group Regulatory Affairs
Robert Åslund, Senior Product Manager Stereotactic Neurosurgery and Stereotactic Radiotherapy
Sören Johansson, Vice President, Business Development, Marketing & Service
Thomas Kraepelien, Senior Physicist & Application Specialist, Research & Development
Ulrika Waltrén, Coordinator Training & System Starts, Education & Training
Vincent Denot, Product Manager Leksell GammaPlan