

The DIVISION of RADIOLOGICAL PHYSICS

September 27, 2007

K-8

Sandy Gabriel

Senior Health Physicist

Medical Branch
NRC Region I

475 Allendale Road

King of Prussia, PA 19406-1415

Fax: 610-337-5269

03030672

Re:

License No. 45-00034-30

Dear Ms. Gabriel;

The University of Virginia requests that the NRC amend License # 45-00034-30 to permit the additional Perfexion Authorized Users (AUs) and Authorized Medical Physicists (AMPs) documented on the attached NRC 313A forms and listed below:

AMPs:

Stanley Benedict, Ph.D., and Carlos Carbini

AUs:

Paul Read, M.D./Ph.D., and Tyvin Rich, M.D.

Elekta's Per Nylund, a physicist board certified in Sweden and Senior Product Manager for the Elekta Gamma Knife Perfexion, has been on-site for the past few days, ensuring these additional people are well trained on Perfexion. The syllabus followed by this trainer is shown in the attached Elekta education & training brochure, "Successful System Start". This training began on Sunday September 23 2007, and has already included observation of at least 3 clinical cases. Since all of those for whom this amendment requests Perfexion AU or AMP status already have previous GSR experience as AUs or AMPs under the "Type C" portion of U.Va.'s license, the Elekta trainer has been free to concentrate on more advanced and Perfexion-specific aspects.

In addition to receiving the on-site vendor-based training mentioned above, training was provided by a Perfexion RSO and AMP previously approved by Elekta in Stockholm (Dr. Alan Aqualino), by a Perfexion AU previously trained through Elekta in Marseille (Dr. James M. Lamer, M.D.), by a U.Va. Dosimetrist (Dr. David Schlesinger) who has explored the new GammaPlan system since being trained on Perfexion in a February 2007 Stockholm class, and by a U.Va. Neurosurgeon (Dr. Jason Sheehan, Ph.D./M.D.) who has treated thousands of patients on previous model GSRs and who received clinical training specific to Perfexion in an Elekta-run Marseille class documented in previous submissions to the NRC.

In particular, each person being requested for AU status has been trained in:

- Perfexion operation
- Safety procedures, including emergency drills
- Clinical use, and

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NMSS/RGN1 MATERIALS-002

 Clinical differences between Perfexion and other GSR units for which they are licensed.

Similarly, each person being requested for AMP status has been trained in:

- Hands-on Perfexion operation
- · Safety procedures, including emergency drills
- Clinical use
- Operation of the Gamma Plan Treatment Planning System, and
- Differences between Perfexion and other GSR units for which they are licensed.

It is hoped that the attached documentation provides the needed information associated with this amendment request. Thank you for your assistance.

Respectfully submitted by

Leonard W. Sandridge

Executive Vice President and Chief Operating Officer

University of Virginia

Ralph O. Allen, Ph.D.

Radiation Safety Officer, University

Alan Aqualino

Chairman, Radiation Safety Committee

Professor, Chemistry

Alan Aqualino, Ph.D.

Radiation Safety Officer, Gamma Knife Unit

Associate Professor, Radiation Oncology

Voice: 434-982-0152

Fax: 434-983-3520

e-mail: AA2H@virginia.edu

September 27, 2007

As a board-certified Swedish Physicist and Senior Product Manager for Leksell Gamma Knife Perfexion, I provided vendor-based on-site training at the University of Virginia between 23-27 September 2007. As detailed in the attached brochure, this training included:

- Perfexion Operation
- Safety procedures, including emergency drills
- Aspects of clinical use
- Operation of Leksell GammaPlan treatment planning system (V8.x), and
- Differences between Perfexion and the previous GSR units on which those being trained had experience.

Those who attended these various training sessions included:

Alan Aqualino, Ph.D.
Stanley H. Benedict, Ph.D.
Carlos Carbini
Marion Harding, R.T.T.
James M. Larner, M.D.
Paul W. Read, M.D./Ph.D
Tyvin Rich, M.D.
David Schlesinger, Ph.D.
Chen Po Yen, M.D.

Attested to by:

Per Nylund

Senior Product Manager, Leksell Gamma Knife

Kungstengatan 18, Box 7593

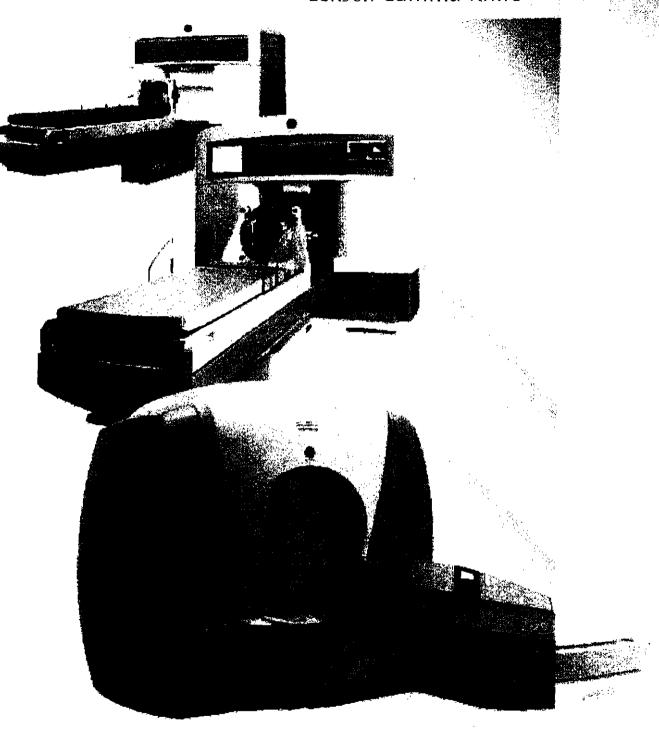
SE-103 93 Stockholm, Sweden

e-mail: Per.Nylund@Elekta.com

No. 2871 P. 5

EDUCATION & TRAINING

Leksell Gamma Knife®



Successful system start





Objective

Elekta provides clinical and technical application support on Leksell Gamma Knife. It is held on-site for all new installations and upgrades of Leksell Gamma Knife.

The System Start takes place during the first week of patient treatments and is the final step in the training process.

The objective of the System Start is to provide confidence in daily clinical practice.

The start-up team consists of one neurosurgeon and one physicist that have extensive experience of Gamma Knife® surgery. These consultants are trained and certified by Elekta.

The consultants will give new users the opportunity to enhance their competence within treatment planning, as well as assist the clinicians in being proficient in the use of their equipment. For upgrade customers a physicist will conduct the training.

Suggested schedule

Day 1

Case conference – to select patients and decide the order of treatments. Ensure that Leksell Gamma Knife® and Leksell GammaPlan® systems are ready for use.

Check connectivity with the radiological department. Before the first patient is treated, ensure that the following procedures have been covered:

- technical training and performance of Emergency Procedures
- function test of Leksell Gamma Knife®
- QA procedures.

Day 2

Treatment of 1 to 2 patients. Practice of the different routines. Discussions on treatment documentation, technical and quality assurance log book.

Day 3

Treatment of 1 to 2 patients.

Time to go through the routines, practice cases and the treatment planning procedure.

Day 4

Treatment of 1 to 2 patients.

Special training on treatment of less common indications and additional dose planning practice.

Clinical lectures by the systems start consultants (optional and done on request).

Day 5

Treatment of 1 to 2 patients. Summary of the System Start.

Requirements for a successful System Start

Secure a start-up date with all responsible people on site Give six weeks notice of the proposed date, in order for Elekta to arrange and book resources Schedule a minimum of five patients, preferably covering a variety of indications.

Further information

Please contact: info.education@elekta.com

Liability

Elekta collaborates with leading faculties world wide to provide education and training. Elekta does not take any responsibility for clinical advice given during these training sessions.

Fighting serious disease

www.elekta.com

Stereotactic Neurosurgery Gamma Knife" surgery # Functional Mapping # Precision Radiation Therapy # Image Guided Radiation Therapy # Stereotactic Radiation Therapy

Stockholm, Sweden Tel ~46 8 587 254 00 FAX -46 8 587 255 00

Worldwide Product Support Center Tel +46 8 587 254 00 x +46 8 587 255 00 info neuro@elekta.com North America Atlanta, USA Tel +1 770 300 9725 info,america@elekta.com

Europe, South America Airica & the Middle East Tel +44 1293 654068 ax -44 1293 654655 Info.europe@elekta.com Jupan Kobe, legan Tel +81 76 241 7100 Fax -81 78 271 7823 info.tapan@elekta.com

Asia PeciliC Hong Kong. China Tel +852 2891 2208 Fax +852 2579 7133 info.asia@elekta.com

NR(Ę٥	DRM 313A (AMP) U.S. NUCI	EAR REGULATORY COMMISSION	
A	U1			APPROVED BY OMB: NO. 3150-012 EXPIRES: 10/31/2008
Nar	10 0	of Proposed Authorized Medical Physicist		
		CARLOS H. CARB	ENI	
Aut	ho	rization(s)	=	• •
		• • • • • • • • • • • • • • • • • • • •		
date req	e of uire	f application or the indlyldual must have obtained relied training and experience was completed. Provide (ated continuing education and	experience since the
AND PRECEPTOR ATTESTATION EXPIRES: 10/S1/2008				
	a.	Provide a copy of the board certification.		
i	b.		er and dates of training for each	type of use for which
	C.	Skip to and complete Part II Preceptor Attestation.	•	
Ø	2.	Current Authorized Medical Physicist Seeking A	dditional Authorization for u	se(s) checked above
_	a.	Go to the table in section 3.c. to document training	for new device.	
	b.	Skip to and complete Part II Preceptor Attestation		
	3.	Education, Training, and Experience for Propos	ed Authorized Medical Physi	<u>clst</u>
	a.			ner physical science,
	D€	egree	Major Field	
	Ł			
	Co	allege or University		
	b.	high-energy external beam therapy (photons and e		
		Yes. Completed 1 year of full-time training in m	edical physics (for areas identi	fied below) under the
		supervision of	who meets the requir	ements for an
		Authorized Medical Physicist.		
		A	ND	
		Yes. Completed 1 year of full-time work experie	ance in madical physics (for an	we identified below)
			who me	•
		an Authorized Medical Physicist.		om and indamation in

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (condition) 3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued) b. Supervised Full-Time Medical Physics Training and Work Experience (continued) If more than one supervising Individual is necessary to document supervised training, provide multiple conditions.						
it more than one supervising ind this page.	IVIOUALIS NECOSSALY to document supervisor	IIIg, promee	luitipio vopios 2.			
Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*			
Medical Physics						
Performing sealed source leak tests and inventories						
Performing decay corrections		:				
Performing full calibration and periodic spot checks of external beam treatment unit(s)						
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)						
Performing full calibration and periodic spot checks of remote afterloading unit(s)						
Conducting radiation surveys around external beam treatment unit(s), sterotactic radiosurgery unit(s), remote after loading unit(s)						
Supervising Individual**	License/Permit Number listing s authorized Medical Physicist	supervising ind	ividual as an			
for the following types of use:		*********	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
Remote afterloader unit(s)	Teletherapy unit(s) Gamma sta	areotactic radi	losurgery unit(s)			
Training and work experience must be or	conducted in clinical radiation facilities that provide high-energy equal to 1 million electron volts) and brachytherapy services.	external beam t	nerapy (photons and			
	aqual to 1 million electron volts) and brachytherapy services. Ingland 1 year of full time work experience cannot be concurse.	AI.				
" If the supervising medical physicist is not	of an authorized medical physicist, the licensee must submit evince requirements in 10 CFR 35.51 and 35.59 for the types of us	idence that the s	upervising medical individual is seeking			

Education, Training	and Experience for Proj	posed Authorized Medical Ph	ysicist (continued)
c. Describe training p	provider and dates of traini	ing for each type of use for whic	ch authorization is sought.
Description of Training		Training Provider and Da	tes
	Remote Afterloader	Teletherapy	Per Sexion Specification Stereotactic Radiosurgery
Hands-on device operation			Worked with Perfexion RSO/Amp 9/17/07-Per Vendor based on-sile 9/23-9/27/07
Safety procedures for the device use			Worked with Perexion RSO/Amp 9/17/07-Pi Vendor based on sle 9/23-9/27/07
Clinical use of the levice			Worked with Persexion RSO/AMA 9/17/07-Pres Vendor based on-sik 9/23-9/27/07
Freatment planning system operation			Self exploration May 2007 - Present Vendor based on-sile 9/23-9/27/07
ioviciai is recoesary to document iis page.)	Medical Pyeicied, (If more than one superior automotive multiple copies of UALING Ph.	Medical Physicist	supervising individual as an authorize $034-30$
Remote afterloade		erapy unit(s) 🔀 Gam	ma stereotactic radiosurgery unit(s)
f Applicable:			
Authorization Soug	ght Device	Training Provide	ed By Dates of Training
5.400 Ophthalmic Us	e		

NRC FC (10-2006)	ORM 313A (AMP)		U.S. NUCLEAR REGULATORY COMMISSION
	ORIZED MEDICA	PHYSICIST TRAINING AND EXPE	RIENCE AND PRECEPTOR ATTESTATION (continue
,		PART II - PRECEPTO	R ATTESTATION
Note:	individual as long	as the preceptor provides, directs, or	tor. The preceptor does not have to be the supervising verifies training and experience required. If more than btain a separate preceptor statement from each.
	Section		
Check	one of the follow	_	
	1. Board Certific	<u>atlon</u>	
	l attest that	Norman of Drawn and Australia Madlant Dhusining	has satisfactorily completed the requirements in
	10 CFR 35.51	Name of Proposed Authorized Medical Physicist a)(1) and (a)(2).	Carlos Carbini was identified as an AMP on a Georgia license (See 10CFR35.57 (a))
	2. Education, Tr	tining, and Experience	(See 10CFR35.57 (a))
,	l attest that		has satisfactorily completed the 1-year of full-time
		Name of Proposed Authorized Medical Physicist	·
	training in med 35.51(b)(1).		ffull-time work experience as required by 10 CFR as AMP for Type C GSRs)
		ANI	
	d Section lete the following:	7314	,
	attest that	Carlos H. Carbini Name of Proposed Authorized Medical Physicist	has training for the types of use for which authorization
	is sought that treatment plan		afety procedures, clinical use, and the operation of a
		AND	*
	Section ete the following:	AND	•
	attest that	Carlos H. Carbini Name of Proposed Authorized Medical Physicist	has achieved a level of competency sufficient to
	function indep	ndently as an Authorized Medical Ph	nysicist for the following:
	35.400 Op	nthalmic use of strontium-90 🔲 35	i.600 Teletherapy unit(s)
- 	=		.600 Gamma stereotactic radiosurgery unit(s)
		AND	
	Section ete the following t	or preceptor attestation and signat	
	I meet the req Medical Physic	frements in 10 CFR 35.51, or equivalist for the following:	lent Agreement State requirements for Authorized
	35,400 Op	hthalmic use of strontium-90 🔲 35	.600 Teletherapy unit(s)
		note afterloader unit(s)	
Name of	Preceptor	Signature	Telephone Number Date
<u>A</u>	LAN HOU	LIND Alas A	4349820152 9/27/07
	/Permit Number/Facil 45-00034	·	+ Virginia Gamma Knife
		=	PAG

NRC (10-20		RM 313A (AMP) U.S. NUCLE	AR REGULATORY COMMISSION					
A	UT	HORIZED MEDICAL PHYSICIST TRAINING AND PRECEPTOR ATTESTAT [10 CFR 35.51]		APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008				
Nan	ie o	f Proposed Authorized Medical Physicist						
	-	STANLEY H. BENEDICT.	Ph.D.					
		sted 35,400 Ophthalmic use of stront	um-90 35.600 Telethera	py unit(s)				
		all that apply) 35.600 Remote afterloader unit(_	stereotactic radiosurgery unit(s)				
			AND EXPERIENCE aree methods below)					
date	ille of	ng and Experience, including Board Certification, mus application or the individual must have obtained relat d training and experience was completed. Provide deperience related to the uses checked above.	ed continuing education and	experience since the				
	1.	Board Certification						
	a.	Provide a copy of the board certification.						
	b.	Go to the table in 3.c. and describe training provider and dates of training for each type of use for which authorization is sought.						
l	c.	Skip to and complete Part II Preceptor Attestation.						
M	2.	Current Authorized Medical Physicist Seeking Ad	ditional Authorization for u	se(s) checked above				
' `	a.	Go to the table in section 3.c. to document training for	r new device.					
	b.	Skip to and complete Part II Preceptor Attestation						
	3.	Education, Training, and Experience for Proposed	i <u>Authorized Medical Physi</u>	<u>cist</u>				
	a,	Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.						
	De	gree	Major Field					
,	L							
	Co	ollege or University						
]			·					
! !	b.	Supervised Full-Time Medical Physics Training and high-energy external beam therapy (photons and electron volts) and brachytherapy services.						
		Yes. Completed 1 year of full-time training in me	dical physics (for areas ident	Ifled below) under the				
İ		supervision of						
		Authorized Medical Physicist.		•				
		Al	ND					
		Yes. Completed 1 year of full-time work experien	nce in medical physics (for ar	eas identified below)				
			who me	_				
		an Authorized Medical Physicist.						

b. Supervised Full-Time Medical Ph	nce for Proposed Authorized Medical Physicist hysics Training and Work Experience (continued) ividual is necessary to document supervised training	-	
Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics			
Performing sealed source leak tests and inventories		·	
Performing decay corrections			
Performing full calibration and periodic spot checks of external beam treatment unit(s)			
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)			
Conducting radiation surveys around external beam treatment unit(s), sterotactic radiosurgery unit(s), remote after loading unit(s)			
Supervising individual**	License/Permit Number listing s authorized Medical Physicist	supervising ind	lividual as an
for the following types of use:	<u>i</u>	•••••	.
Remote afterloader unit(s)	Teletherapy unit(s) Gamma ste	reotactic rad	losurgery unit(s)
	onducted in dinical radiation facilities that provide high-energy qual to 1 million electron volts) and brachytherapy services.	external beam f	herapy (photons and
 1 year of Full-time medical physics training 	ng and 1 year of full time work experience cannot be concurren	nt.	

		EXPERIENCE AND PRECE ed Authorized Medical Physic	SPTOR ATTESTATION (continued) sicist (continued)	
-	•	for each type of use for which		
Description of Training Provider and Dates				
	Remote Afterloader	Teletherapy	Per Jexfon Specific Gamma Stereotactic Radiosurgery	
Hands-on device operation			Worked with Perfexion R\$0/Amp 9/24/07-Present Vendor based on-sile 9/26-9/27/07	
Safety procedures or the device use			Worked with Perfexion RSO/AMP 9/24/07-Perf Vendor based on-sile 9/26-9/27/07	
Clinical use of the device	·		worked with fersenon PSO/Amp and with vendor-based on-site trainer 9/26-9/27/07	
Treatment planning system operation			worked with Vender's on-sile trainer and licensee's Perfesion Dasinet	
Supervising Individual resiring is provided by Supervising is advidual is necessary to document as its page.)	dedical Pysicist, (if more than one supervising upervised training, provide multiple copies of	License/Permit Number listing s Medical Physicist	supervising individual as an authorized	
ALAN Por the following types of	DOUALTNO, Ph.D.	. 	00034-30	
Remote afterloader	unit(s) Telethera		na stereotactic radiosurgery unit(s)	
f Applicable:				
Authorization Sougi	nt Device	Training Provided	By Dates of Training	
i5.400 Ophthalmic Use of strontium-90				

NRC FORM 313A (AMP) U.S. NUCLEAR REGULATORY COMMISSION
(10-2005) AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
PART II ~ PRECEPTOR ATTESTATION
Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.
First Section Check one of the following:
1. Board Certification
Name of Proposed Authorized Medical Physiciat
10 CFR 35.51(a)(1) and (a)(2).
OR 2. Education, Training, and Experience
I attest that Stanley H. Benedict has satisfactorily completed the 1-year of full-time
training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).
AND
Second Section Complete the following:
Name of Proposed Authorized Medical Physician
is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.
AND
Third Section
Complete the following:
Name of Proposed Authorized Medical Physician
function independently as an Authorized Medical Physicist for the following:
35.400 Ophthalmic use of strontium-90 35.600 Teletherapy unit(s)
35.600 Remote afterloader unit(s) 35.600 Gamma stereotactic radiosurgery unit(s)
AND
Fourth Section Complete the following for preceptor attestation and signature:
I meet the requirements in 10 CFR 35.51, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:
35.400 Ophthalmic use of strontium-90 35.600 Teletherapy unit(s)
35.600 Remote afterloader unit(s) 35.600 Gamma stereotactic radiosurgery unit(s)
Name of Preceptor ALAN AGUALINO Han Agualino Telephone Number Date 9/27/07
License/Permit Number/Facility Name 45-00034-30 University of Virginia Gamma Krife

NRC FORM 313A (AUS) 5-2007)	U.S. NUCLEAR REGULATORY COMMISSI	ION	
	TRAINING AND EXPERIENCE		Y OMB: NO. 3150-0120
(for uses defined	d under 35.400 and 35.600)	EXPIRES: 10/3	11/2008
[10 CFR 35.49	90, 35.491, and 35.690]		
Name of Proposed Authorized User	State or Territory Where Llo	ensed	
	M.D. /ph.D. Virginia		· · · · · · · · · · · · · · · · · · ·
reducated	anual brachytherapy sources 35.600 Teleti		- 9461
Check all that addiv! 💳	ohthalmic use of strontium-90 35.600 Gamr	ma stereotactic rad	diosurgery unit(8)
35.50U Ke	emote afterloader unit(s)		
	PART I TRAINING AND EXPERIENCE (Select one of the three methods below)		
date of application or the individua	g Board Certification, must have been obtained al must have obtained related continuing educat was completed. Provide dates, duration, and de s checked above.	ition and experienc	cé since the
1. Board Certification			
a. Provide a copy of the board cel	rtification.		
 For 35.600, go to the table in 3 which authorization is sought. 	3.e. and describe training provider and dates of t	training for each ty	ype of use for
c. Skip to and complete Part II Pre	eceptor Attestation.		
2. <u>Current 35,600 Authorized Use</u>	er Requesting Additional Authorization for 3	i5.600 Use(s) Che	ecke <u>d Above</u>
	to document training for new device.		
b. Skip to and complete Part II Pre	-		
3. Training and Experience for P	•		
a. Classroom and Laboratory Train		35.690	
Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
	Total Hours of Training:		
l l			1.7

Training and Experience for Propo	sed Authorized User (cor	itinued)		
b. Supervised Work and Clinical Exp necessary to document supervised w	erience for 10 CFR 35.490	(If more than one	e supervising indi is page.)	vidual is
Supervised Work Experience	· · · · · · · · · · · · · · · · · · ·	Total Hours of Experience:		
Description of Experience Must Include:	Location of Experience Permit Number of	-/License or	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			Yes No	
Checking survey meters for proper operation			Yes No	
Preparing, implanting, and safely removing brachytherapy sources			☐ Yes ☐ No	
Maintaining running inventories of material on hand			Yes No	
Using administrative controls to prevent a medical event involving the use of byproduct material			Yes No	
Using emergency procedures to control byproduct material			Yes No	
Clinical experience in radiation oncology as part of an approved formal training program		erience/License	or	Dates of Experience*
Residency Review Committee for Radiation Oncology of the ACGME Royal College of Physicians and Surgeons of Canada Committee on Postdoctoral				
Training of the American Osteopathic Association Supervising Individual			ng supervising indi	

FORM 313A (AUS) AUTHORIZED USER TRAINING	G AND EXPERIENCE AND PRECEPTOR AT		ATORY COMMISS ontinued)				
Training and Experience for Propos	sed Authorized User (continued)						
c. Supervised Clinical Experience for 10 CFR 35.491							
Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience				
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history							
Supervising Individual	License/Permit Number listin Authorized User	ing supervising ind	lividual as an				
d. Supervised Work and Clinical Expe	erience for 10 CFR 35.690						
Remote afterloader unit(s)		na stereotactic ra	idiosurgery uni				
Supervised Work Experience	Total Hours of Experience:						
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience				
Reviewing full calibration measurements and periodic spot-checks		Yes No					
Preparing treatment plans and calculating treatment doses and times		Yes No					
Using administrative controls to prevent a medical event nvolving the use of byproduct material		☐ Yes					
mplementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		☐ Yes					
Checking and using survey meters		Yes No					
Selecting the proper dose and how it is to be administered		☐ Yes					

Training and Experience for Proposed Authorized User (continued) d. Supervised Work and Clinical Experience for 10 CFR 35,690 (continued)						
Clinical experience in radiation oncology as part of an approved formal training program Approved by: Residency Review Committee for Radiation Oncology of the ACGME Royal College of Physicians and Surgeons of Canada Committee on Postdoctoral Training of the American Osteopathic Association		Location of Experience/License or Permit Number of Facility			Dates of Experience*	
					;	
Supervising Individual	<u> </u>		License/Permit Number Authorized User	listing supervising ind	lividual as an	
Description of Training Remote Af			raining Provider and Dat	Gamma	Stereotactic osurgery	
Device operation	Remote Afterloa	der	Teletherapy	Radio		
				Persex	100 AU A	
Safety procedures for the device use				Vendor Persexion	and by 1 AU, AMP	
1				9/24-9, Vendor	and by 1 AU, AMP 127/07 by and by M AU	
			ense/Permit Number (Isting thorized User			
device Supervising Individua Individual (If more than or to document supervised w	e supervising individual i	nuitiple				
Clinical use of the device Supervising Individual Individual (If more than or to document supervised we copies of this page.) James Authorized for the following the copies of the supervised we copies of this page.	e supervising individual i ork experience, provide n M. Larnes	nuitiple	45-00	0034-30)	

NRC FO	ORM 313A (AUS)		U.S, NUCLEAR REGULATORY COMMISSION
(3-5007)	AUTHORIZED US	ER TRAINING AND EXPERIEN	CE AND PRECEPTOR ATTESTATION (continued)
		PART II PRECEP	TOR ATTESTATION
Note:	individual as long as	s the preceptor provides, directs,	ceptor. The preceptor does not have to be the supervising , or verifies training and experience required. If more than b, obtain a separate preceptor statement from each.
	Section cone of the following	g for each requested authoriza	ation:
For 3	35.490 <u>:</u>		
<u> </u>	Board Certification	•	
i t	l attest that		has satisfactorily completed the requirements in
٠.			tency sufficient to function independently as an es for the medical uses authorized under 10 CFR 35.400.
,		C	DR Comments
IJ	raining and Experien	<u>ice</u>	•
	i attest that		has satisfactorily completed the 200 hours of
<u>For 3</u>	 clinical experience level of compete 	ce in radiation oncology, as requ	supervised work experience, and 3 years of supervised ulred by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a ndently as an authorized user of manual brachytherapy 0 CFR 35.400.
	[] attest that		has satisfactorily completed the 24 hours of
	has used strontic	m-90 for ophthalmic treatment of	he medical use of strontium-90 for ophthalmic radiotherapy, of 5 individuals, as required by 10 CFR 35.491(b), and has tion independently as an authorized user of strontium-90 for
A			
•	nd Section <u>5.690:</u>		. If
	oard <u>Cert</u> ification		
<u> </u>	attest that	Paul W. Poal	has satisfactorily completed the requirements in
	<u></u>	Name of Proposed Authorized User	
	35.690(a)(1).	_	_
	raining and Experie		PR
	I attest that		has satisfactorily completed 200 hours of classroom
			of work experience, and 3 years of supervised clinical 10 CFR 35.690(b)(1) and (b)(2).
		AN	ID

NRC FORM 313A (AUS) U.S. NUCLEAR REGULATORY COMMISSION
(5-2007) AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation (continued)
Third Section
<u>For 35.690:</u> (continued)
Name of Proposed Authorized User has received training required in 35.690(c) for device
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.
Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)
AND
Fourth Section
lattest that Paul W. Read has achieved a level of competency sufficient to
achieve a level of competency sufficient to function independently as an authorized user for:
Remote afterloader unit(s) Teletherapy unit(s) Samma stereotactic radiosurgery unit(s)
Fifth Section
Complete the following for preceptor attestation and signature:
I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:
35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)
35.400 Ophthalmic use of strontium-90 X 35.800 Gamma stereotactic radiosurgery unit(s)
35.600 Remote afterloader unit(s)
Name of Preceptor Signature Telephone Number Date
JAMES M. LARNER MD MW 4349245564 9/26/07
License/Permit Number/Facility Name
45-00034-30 University of Virginia Gamma Knife
~ ~

NRC FORM 313A (AUS) (3-2007)		U.S. NUCL	EAR REGULATORY O	COMMISSION		
(for u	AND PRECEI	TRAINING AND PTOR ATTESTA under 35.400 ar 30, 35.491, and 3	ATION nd 35.600)		APPROVED BY EXPIRES: 10/31	r OMB: NO. 3150-0120 11/2008
Name of Proposed Author	_	44 0	State or Territory V		ed	
TYVIN				ginla		
Requested	_	nual brachytherapy s	=		,	
Authorization(s) (check all that apply)	=	hthaimic use of stron	, _)0 Gamma :	atereotactic rac	(a)mnu yisgruzoit
		mote afterloader unit		NAE		
		PART I - TRAININ (Select one of the				
date of application	or the individual nd experience w	g Board Certification, al must have obtained vas completed. Prov s checked above,	d related continuin	ng education	and experience	ce since the
1. Board Certificat	<u>tlon</u>					
a. Provide a copy of	of the board cer	rtification.				
b. For 35.600, go to which authorizate		.e. and describe train	ning provider and o	dates of train	ning for each ty	/pe of use for
c. Skip to and com	iplete Part II Pre	eceptor Attestation.				
2. <u>Current 35.600 A</u>	uthorized Use	r Requesting Addit	ional Authorizati	on for 35.6(00 Use(s) Che	cked Above
		o document training				
b. Skip to and com	iplete Part II Pre	eceptor Attestation.				
3. Training and Ex	perlence for P	roposed Authorize	d User			•
a. Classroom and t	Laboratory Train	ining 35.490	35.491	35.6	390	
Description of	Training	Local	tion of Training		Clock Hours	Dates of Training*
Radiation physics a instrumentation	ind					
Radiation protection	1					·
Mathematics pertain use and measurement radioactivity						
Radiation biology						
		Total Hours	of Training:			

Training and Experience for Propos	ed Authorized User (cor	ntinued)		
b. Supervised Work and Clinical Expensessary to document supervised we	rience for 10 CFR 35.490 ork experience, provide mu	(If more than one altiple copies of th	a supervising indiv is page.)	vidual is
Supervised Work Experience		Total Hours of Experience:		
Description of Experience Must Include:	Location of Experience Permit Number of	e/License or	Confirm	Dates of Experience
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			☐ Yes	
Checking survey meters for proper operation			Yes No	
Preparing, implanting, and safely emoving brachytherapy sources			Yes No	
Maintaining running inventories of material on hand			Yes No	
Using administrative controls to prevent a medical event nvolving the use of byproduct naterial			Yes No	
Using emergency procedures to control byproduct material			Yes No	
Clinical experience in radiation oncology as part of an approved formal training program		perience/License nber of Facility	or	Dates of Experience
Approved by:		<u></u>		
Residency Review Committee for Radiation Oncology of the ACGME				
Royal College of Physicians and Surgeons of Canada				
Committee on Postdoctoral Training of the American Osteopathic Association				
Supervising Individual	License, Authoriz		ing supervising Ind	ividual as an

AUTHORIZED USER TRAINING Training and Experience for Propo			
c. Supervised Clinical Experience for			
Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual	License/Permit Number lis Authorized User	ting supervising ind	lividual as an
d. Supervised Work and Clinical Expe	erience for 10 CFR 35,690		
Remote afterloader unit(s)		ma stereotactic ra	idlosurgery un
Supervised Work Experience	Total Hours of Experience:		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience
Reviewing full calibration measurements and periodic spot-checks		☐ Yes ☐ No	
Preparing treatment plans and calculating treatment doses and times		Yes No	
Using administrative controls to prevent a medical event involving the use of byproduct material		Yes No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		☐ Yes ☐ No	
Checking and using survey meters		Yes No	
Selecting the proper dose and how it is to be administered		Yes	

THE PERSON NAMED IN COLUMN 1	rience for Propose	d Authorized	User (continued)		
d. Supervised Worl	k and Clinical Experie	ence for 10 C	FR 35.690 (continued)		
Clinical experienc oncology as part o formal training	f an approved	Loc	cation of Experience/Lice Permit Number of Facil		Dates of Experience*
Approved by:					
Residency Rev Committee for i Oncology of the	Radiation EACGME of Physicians				
and Surgeons of Committee on Family of the Costeopathic As	Postdoctoral American				
Supervising Individua	al .		License/Permit Numb Authorized User	er listing supervising in	dividual as an
Description of Training			Training Provider and D	ates	
of Training	Remote Afterio	pader	Training Provider and D	Gamma	a Stereotactic
of Training	Remote Afterio	pader		Gamma Rad	losurgery
of Training Device operation Safety procedures	Remote Afterio	oader		Gamma Rad 9/24-9/ Vendor Persexii 9/24-5 Vendor Persexio	105urgery 127/07 by 2 and by 3/27/07 by and by And by And by And by
of Training Device operation	Remote Afterio	pader		Gamma Rad 9/24-9/ Vendor Persexii 9/24-9/ Vendor Persexion 9/24-9/	105urgery 127/07 by 107/07 by
of Training Device operation Safety procedures for the device use Clinical use of the device Supervising Individual (If more than	Remote Afterio	by Supervising		Gamma Rad 9/24-9/ Vendor Persexia 9/24-9/ Vendor Persexia 9/24-9/ Vendor Persexia	losurgery 127/07 by and by AND AND AND AND BY
of Training Device operation Safety procedures for the device use Clinical use of the device Supervising Individual (If more than to document supervised copies of this page.)	ual. If training provided I	by Supervising of is necessary a multiple	Teletherapy License/Permit Number list Authorized User	Gamma Rad 9/24-9/ Vendor Persexia 9/24-9/ Vendor Persexia 9/24-9/ Vendor Persexia	losurgery 127/07 by and by 1/27/07 by And by And by Au + Am 1/27/07 by and by

NRC FORM 313A (AUS)		U.S. NUCLEAR REGULATORY COMMISSION
(3-2007) AUTH(ORIZED US	ER TRAINING AND EXPERIENC	E AND PRECEPTOR ATTESTATION (continued)
individu	al as long a:	s the preceptor provides, directs,	aptor. The preceptor does not have to be the supervising or verifies training and experience required. If more than
one pre First Section	ceptor is ne	cessary to document experience,	obtain a separate preceptor statement from each.
	he following	g for each requested authorizat	ion:
<u>For 35,490:</u>			
Board Cer	rtification		
∏ l atte	est that	Name of Proposed Authorized User	has satisfactorily completed the requirements in
35.4 auth	90(a)(1) and orized user	d has achieved a level of compete	ency sufficient to function independently as an services for the medical uses authorized under 10 CFR 35.400.
		O	R
<u>Training a</u>	nd Experier	<u>1C0</u>	
1 atte	est that		has satisfactorily completed the 200 hours of
clinic level	cal experiend of compete	ce in radiation oncology, as requir	upervised work experience, and 3 years of supervised red by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a dently as an authorized user of manual brachytherapy CFR 35.400.
For 35.491:			
l atte	est that		has satisfactorily completed the 24 hours of
has l achle	used strontil	um-90 for ophthalmic treatment of	e medical use of strontium-90 for ophthalmic radiotherapy, f 5 indlvIduals, as required by 10 CFR 35.491(b), and has ion independently as an authorized user of strontium-90 for

Second Section	on		
For 35,690:			
Board Cer	tification		
l atte	est that	Name of Proposed Authorized User	has satisfactorily completed the requirements in
35.6	90(a)(1).	_	
Training	and Experie	OI ence	R
_	ttest that		has satisfactorily completed 200 hours of classroom
		Name of Proposed Authorized User training, 500 hours of supervised adiation therapy, as required by 1	work experience, and 3 years of supervised clinical O CFR 35.690(b)(1) and (b)(2).
		AN	D

NRC FORM 313A (AUS) U.S. NUCLEAR REGULATORY COMMISSION
(5-2007) AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation (continued)
Third Section
For 35.690: (continued)
I attest that Proposed Authorized User has received training required in 35.690(c) for device
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.
Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)
AND
Fourth Section
I attest that Proposed Authorized User has achieved a level of competency sufficient to
achieve a level of competency sufficient to function independently as an authorized user for:
Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)
Fifth Section
Complete the following for preceptor attestation and signature:
I meet the requirements in 10 CFR 35,490, 35,491, 35,690, or equivalent Agreement State requirements, as an authorized user for:
35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)
☐ 35.400 Ophthalmic use of strontium-90 🄀 35.600 Gamma stereotactic radiosurgery unit(s)
35.600 Remote afterloader unit(s)
Name of Preceptor Tames M. Larner M.D. License/Permit Number/Facility Name Signature W. Signatur
45-00034-30 University of Virginia Gammaknis