

**The DIVISION of RADIOLOGICAL PHYSICS**

September 27, 2007

Sandy Gabriel  
Senior Health Physicist  
Medical Branch  
NRC Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415  
Fax: 610-337-5269

K-8

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 Carhini  
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  
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](mailto: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 Carhini  
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:

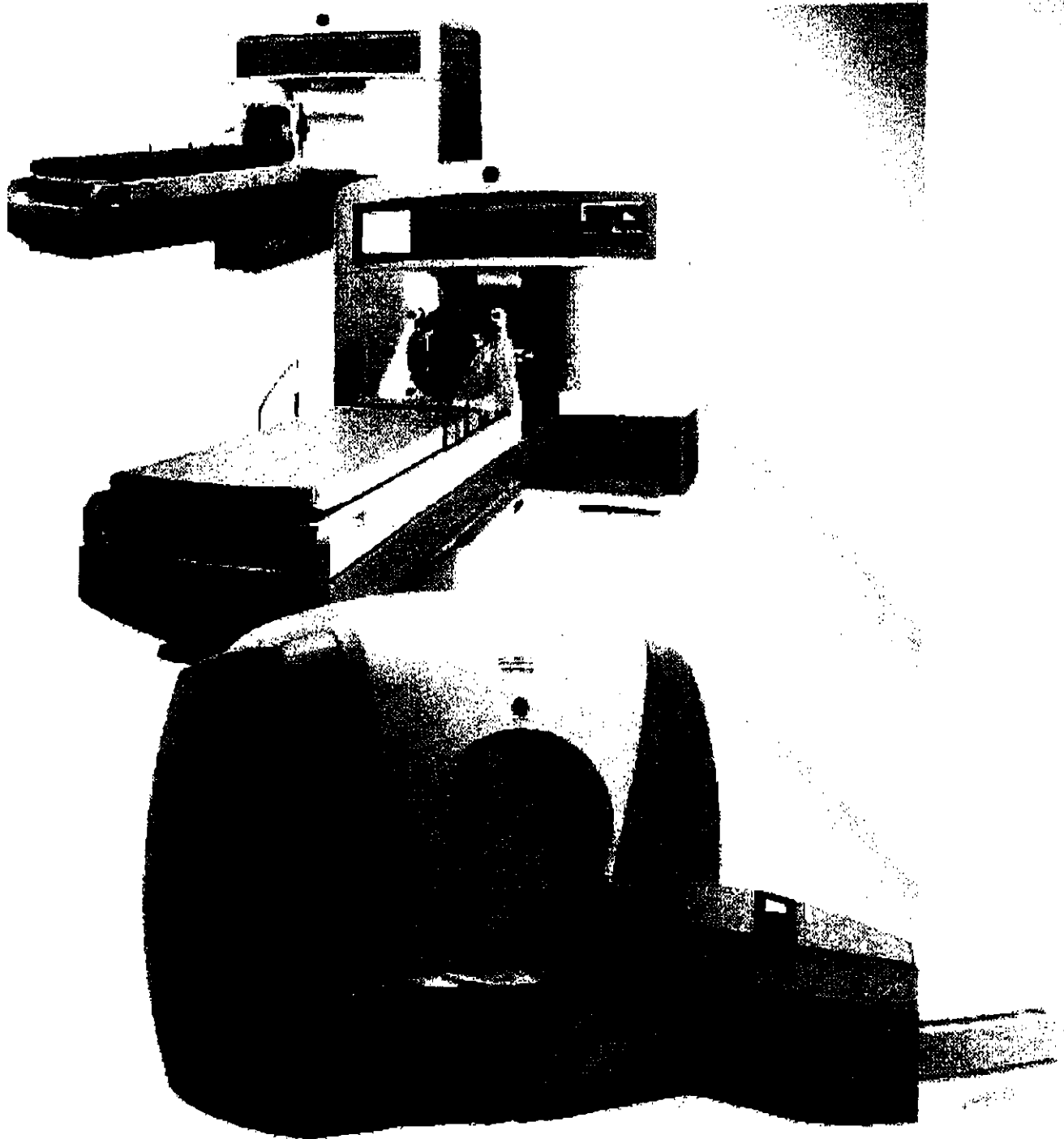


Per Nylund  
Senior Product Manager, Leksell Gamma Knife  
Kungstengatan 18, Box 7593  
SE-103 93 Stockholm, Sweden

e-mail: Per.Nylund@Elekta.com

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

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<b>NRC FORM 313A (AMP)</b> (10-2006)	<b>U.S. NUCLEAR REGULATORY COMMISSION</b>	<b>APPROVED BY OMB: NO. 3150-0120</b> <b>EXPIRES: 10/31/2008</b>						
<b>AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</b> <b>[10 CFR 35.51]</b>								
Name of Proposed Authorized Medical Physicist <div style="font-size: 1.2em; font-family: cursive;">CARLOS H. CARBINI</div>								
Requested Authorization(s) (check all that apply) <input type="checkbox"/> 35.400 Ophthalmic use of strontium-90 <input type="checkbox"/> 35.600 Teletherapy unit(s) <input type="checkbox"/> 35.600 Remote afterloader unit(s) <input checked="" type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s)								
<b>PART I - TRAINING AND EXPERIENCE</b> <i>(Select one of the three methods below)</i>								
*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.								
<input type="checkbox"/> <b>1. Board Certification</b> <ol style="list-style-type: none"> <li>a. Provide a copy of the board certification.</li> <li>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.</li> <li>c. Skip to and complete Part II Preceptor Attestation.</li> </ol>								
<input checked="" type="checkbox"/> <b>2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above</b> <ol style="list-style-type: none"> <li>a. Go to the table in section 3.c. to document training for new device.</li> <li>b. Skip to and complete Part II Preceptor Attestation</li> </ol>								
<input type="checkbox"/> <b>3. Education, Training, and Experience for Proposed Authorized Medical Physicist</b> <ol style="list-style-type: none"> <li>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.</li> </ol> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 50%; padding: 5px;">Degree</td> <td style="width: 50%; padding: 5px;">Major Field</td> </tr> <tr> <td style="height: 40px;"></td> <td></td> </tr> <tr> <td colspan="2" style="padding: 5px;">College or University</td> </tr> </table>			Degree	Major Field			College or University	
Degree	Major Field							
College or University								
b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.								
<input type="checkbox"/> Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.								
<b>AND</b>								
<input type="checkbox"/> Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.								

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(10-2006)

**AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)****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 copies of this page.*

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), stereotactic radiosurgery unit(s), remote after loading unit(s)			

Supervising Individual\*\*

License/Permit Number listing supervising individual as an authorized Medical Physicist

for the following types of use:

☐ Remote afterloader unit(s)☐ Teletherapy unit(s)☐ Gamma stereotactic radiosurgery unit(s)

\* Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

\*\* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

\*\*\* If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

NRC FORM 313A (AMP)  
(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

## AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Perfection Specific Gamma Stereotactic Radiosurgery
Hands-on device operation			Worked with Perfection RSO/Amp 9/17/07 - Present Vendor based on-site 9/23 - 9/27/07
Safety procedures for the device use			Worked with Perfection RSO/Amp 9/17/07 - Present Vendor based on-site 9/23 - 9/27/07
Clinical use of the device			Worked with Perfection RSO/Amp 9/17/07 - Present Vendor based on-site 9/23 - 9/27/07
Treatment planning system operation			Self exploration May 2007 - Present Vendor based on-site 9/23 - 9/27/07

## Supervising Individual

If training is provided by Supervising Medical Physicist, (if more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)

License/Permit Number listing supervising individual as an authorized Medical Physicist

- ALAN AQUILINO, Ph.D.  
for the following types of use:

45-00034-30

45-00034-26

☒ Remote afterloader unit(s)☐ Teletherapy unit(s)☒ Gamma stereotactic radiosurgery unit(s)

Perfection + Model C

If Applicable:

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.



NRC FORM 313A (AMP)  
(10-2006)

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## 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

☐ I attest that \_\_\_\_\_ has satisfactorily completed the requirements in

Name of Proposed Authorized Medical Physicist

10 CFR 35.51(a)(1) and (a)(2).

Carlos Carbini was identified as  
OR an AMP on a Georgia license  
(see 10CFR 35.57(a))

2. Education, Training, and Experience

☐ I attest that \_\_\_\_\_ has satisfactorily completed the 1-year of full-time

Name of Proposed Authorized Medical Physicist

training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

(Already listed as AMP for Type C GSRs)

AND

## Second Section

Complete the following:

☒ I attest that Carlos H. Carbini has training for the types of use for which authorization

Name of Proposed Authorized Medical Physicist

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:

☒ I attest that Carlos H. Carbini has achieved a level of competency sufficient to

Name of Proposed Authorized Medical Physicist

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 AQUALINO

Signature

Alan Aqualino

Telephone Number

434 982 0152

Date

9/27/07

License/Permit Number/Facility Name

45-00034-30

University of Virginia Gamma Knife

<b>NRC FORM 313A (AMP)</b> (10-2006)	<b>U.S. NUCLEAR REGULATORY COMMISSION</b>	<b>APPROVED BY OMB: NO. 3150-0120</b> <b>EXPIRES: 10/31/2008</b>								
<b>AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</b> <b>[10 CFR 35.51]</b>										
<b>Name of Proposed Authorized Medical Physicist</b> <div style="font-size: 1.2em; font-family: cursive;">STANLEY H. BENEDICT, Ph.D.</div>										
<b>Requested Authorization(s)</b> (check all that apply) <input type="checkbox"/> 35.400 Ophthalmic use of strontium-90 <input type="checkbox"/> 35.600 Teletherapy unit(s) <input type="checkbox"/> 35.600 Remote afterloader unit(s) <input checked="" type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s)										
<b>PART I -- TRAINING AND EXPERIENCE</b> (Select one of the three methods below)										
<p>*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.</p>										
<input type="checkbox"/> <b>1. Board Certification</b> 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. c. Skip to and complete Part II Preceptor Attestation.										
<input checked="" type="checkbox"/> <b>2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above</b> a. Go to the table in section 3.c. to document training for new device. b. Skip to and complete Part II Preceptor Attestation										
<input type="checkbox"/> <b>3. Education, Training, and Experience for Proposed Authorized Medical Physicist</b> 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. <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%; padding: 5px;">Degree</td><td style="width: 50%; padding: 5px;">Major Field</td></tr><tr><td colspan="2" style="height: 30px;"></td></tr><tr><td colspan="2" style="padding: 5px;">College or University</td></tr><tr><td colspan="2" style="height: 30px;"></td></tr></table> b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services. <div style="margin-top: 10px;"><input type="checkbox"/> Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.</div> <div style="text-align: center; margin: 10px 0;"><b>AND</b></div> <div style="margin-top: 10px;"><input type="checkbox"/> Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.</div>			Degree	Major Field			College or University			
Degree	Major Field									
College or University										

NRC FORM 313A (AMP)

U.S. NUCLEAR REGULATORY COMMISSION

(10-2006)

**AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)****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 copies of this page.*

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), stereotactic radiosurgery unit(s), remote after loading unit(s)			

Supervising Individual\*\*

License/Permit Number listing supervising individual as an  
authorized Medical Physicist

for the following types of use:

☐ Remote afterloader unit(s)      ☐ Teletherapy unit(s)      ☐ Gamma stereotactic radiosurgery unit(s)

\* Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

\*\* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

\*\* If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

NRC FORM 313A (AMP)  
(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

## AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	
			Perflexion Specific Gamma Stereotactic Radiosurgery
Hands-on device operation			Worked with Perflexion RSO/AMP 9/24/07-Present Vendor based on-site 9/26-9/27/07
Safety procedures for the device use			Worked with Perflexion RSO/AMP 9/24/07-Present Vendor based on-site 9/26-9/27/07
Clinical use of the device			Worked with Perflexion RSO/AMP and with Vendor-based on-site trainer 9/26-9/27/07
Treatment planning system operation			Worked with Vendor's on-site trainer and licensee's Perflexion Dosimetrist 9/26-9/27/07
Supervising Individual <small>If training is provided by Supervising Medical Physicist, (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)</small>		License/Permit Number listing supervising individual as an authorized Medical Physicist	
ALAN AQUALINO, Ph.D.		45-00034-30	
for the following types of use:		45-00034-26	
<input checked="" type="checkbox"/> Remote afterloader unit(s)		<input type="checkbox"/> Teletherapy unit(s)	
		<input checked="" type="checkbox"/> Gamma stereotactic radiosurgery unit(s) Perflexion	

If Applicable:

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

NRC FORM 313A (AMP)  
(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

## 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

☒ I attest that Stanley H. Benedict has satisfactorily completed the requirements in  
Name of Proposed Authorized Medical Physicist  
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  
Name of Proposed Authorized Medical Physicist  
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:

☒ I attest that Stanley H. Benedict has training for the types of use for which authorization  
Name of Proposed Authorized Medical Physicist  
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:

☒ I attest that Stanley H. Benedict has achieved a level of competency sufficient to  
Name of Proposed Authorized Medical Physicist  
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 AQUALINO

Signature

Alan Aqualino

Telephone Number

434 9820152

Date

9/27/07

License/Permit Number/Facility Name

45-00034-30

University of Virginia Gamma Knife

NRC FORM 313A (AUS)  
(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.400 and 35.600)  
[10 CFR 35.490, 35.491, and 35.690]

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: 10/31/2008

Name of Proposed Authorized User

Paul W. Read, M.D./Ph.D.

State or Territory Where Licensed

Virginia

Requested

Authorization(s)

(check all that apply)

☐ 35.400 Manual brachytherapy sources☐ 35.600 Teletherapy unit(s)☐ 35.400 Ophthalmic use of strontium-90☒ 35.600 Gamma stereotactic radiosurgery unit(s)☐ 35.600 Remote afterloader unit(s)

**PART I -- TRAINING AND EXPERIENCE**  
(Select one of the three methods below)

- \* Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ 1. Board Certification

- Provide a copy of the board certification.
- For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
- Skip to and complete Part II Preceptor Attestation.

☒ 2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above

- Go to the table in section 3.e. to document training for new device.
- Skip to and complete Part II Preceptor Attestation.

☐ 3. Training and Experience for Proposed Authorized User

- Classroom and Laboratory Training ☐ 35.490 ☐ 35.491 ☐ 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			
<b>Total Hours of Training:</b>			

NRC FORM 313A (AUS)  
(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)****3. Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

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*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking survey meters for proper operation		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
<b>Approved by:</b> <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

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**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)****3. Training and Experience for Proposed 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 listing supervising individual as an Authorized User	

**d. Supervised Work and Clinical Experience for 10 CFR 35.690**☐ Remote afterloader unit(s)☐ Teletherapy unit(s)☐ Gamma stereotactic radiosurgery unit(s)

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	



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## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 3. 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	Location of Experience/License or Permit Number of Facility	Dates of Experience*
<b>Approved by:</b> <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User

## e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			9/24-9/27/07 by Vendor and by Perfexion AU AMP.
Safety procedures for the device use			9/24-9/27/07 by Vendor and by Perfexion AU, AMP
Clinical use of the device			9/24-9/27/07 by Vendor and by Perfexion AU

Supervising Individual. If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

License/Permit Number listing supervising individual as an Authorized User

James M. Larner, M.D.

45-00034-30

Authorized for the following types of use:

☐ Remote afterloader unit(s)
 ☐ Teletherapy unit(s)
 ☒ Gamma stereotactic radiosurgery unit(s)

## f. Provide completed Part II Preceptor Attestation.

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## AUTHORIZED USER 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 for each requested authorization:

## For 35.490:

## Board Certification

☐ I attest that \_\_\_\_\_ has satisfactorily completed the requirements in  
Name of Proposed Authorized User  
35.490(a)(1) and has achieved a level of competency sufficient to function independently as an  
authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

## Training and Experience

☐ I attest that \_\_\_\_\_ has satisfactorily completed the 200 hours of  
Name of Proposed Authorized User  
classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised  
clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a  
level of competency sufficient to function independently as an authorized user of manual brachytherapy  
sources for the medical uses authorized under 10 CFR 35.400.

## For 35.491:

☐ I attest that \_\_\_\_\_ has satisfactorily completed the 24 hours of  
Name of Proposed Authorized User  
classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy,  
has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has  
achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for  
ophthalmic use.

## Second Section

## For 35.690:

## Board Certification

☒ I attest that Paul W. Read has satisfactorily completed the requirements in  
Name of Proposed Authorized User  
35.690(a)(1).

OR

## Training and Experience

☐ I attest that \_\_\_\_\_ has satisfactorily completed 200 hours of classroom  
Name of Proposed Authorized User  
and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical  
experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

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## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## Preceptor Attestation (continued)

## Third Section

## For 35.690: (continued)

☒ I attest that Paul W. Read has received training required in 35.690(c) for device  
Name of Proposed Authorized User

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 Paul W. Read has achieved a level of competency sufficient to  
Name of Proposed Authorized User

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 ☒ 35.800 Gamma stereotactic radiosurgery unit(s)

☐ 35.600 Remote afterloader unit(s)

Name of Preceptor

Signature

Telephone Number

Date

JAMES M. LARNER, MD

4349245564

9/26/07

License/Permit Number/Facility Name

45-00034-30

University of Virginia Gamma Knife

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<b>AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</b> (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]		

Name of Proposed Authorized User <div style="font-size: 1.2em; font-family: cursive;">TYVIN RICH, M.D.</div>	State or Territory Where Licensed <div style="font-size: 1.2em; font-family: cursive;">Virginia</div>
---	--

<b>Requested Authorization(s)</b> (check all that apply)	<input type="checkbox"/> 35.400 Manual brachytherapy sources	<input type="checkbox"/> 35.600 Teletherapy unit(s)
	<input type="checkbox"/> 35.400 Ophthalmic use of strontium-90	<input checked="" type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s)
	<input type="checkbox"/> 35.600 Remote afterloader unit(s)	

**PART I – TRAINING AND EXPERIENCE**  
(Select one of the three methods below)

\* Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- ☐ 1. Board Certification
- a. Provide a copy of the board certification.
  - b. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
  - c. Skip to and complete Part II Preceptor Attestation.
- ☒ 2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above
- a. Go to the table in section 3.e. to document training for new device.
  - b. Skip to and complete Part II Preceptor Attestation.
- ☐ 3. Training and Experience for Proposed Authorized User
- a. Classroom and Laboratory Training ☐ 35.490 ☐ 35.491 ☐ 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			
<b>Total Hours of Training:</b>			

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**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)****3. Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

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*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking survey meters for proper operation		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
<b>Approved by:</b> <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

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**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)****3. Training and Experience for Proposed 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 listing supervising individual as an Authorized User	

**d. Supervised Work and Clinical Experience for 10 CFR 35.690**☐ Remote afterloader unit(s)☐ Teletherapy unit(s)☐ Gamma stereotactic radiosurgery unit(s)

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

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## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. 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	Location of Experience/License or Permit Number of Facility	Dates of Experience*
<b>Approved by:</b> <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User

## e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			9/24-9/27/07 by Vendor and by Perfexion AU + AMP
Safety procedures for the device use			9/24-9/27/07 by Vendor and by Perfexion AU + AMP
Clinical use of the device			9/24-9/27/07 by Vendor and by Perfexion AU
Supervising Individual. If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)		License/Permit Number listing supervising individual as an Authorized User	
James M. Larner, M.D.		45-00034-30	
Authorized for the following types of use:			
<input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input checked="" type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

## f. Provide completed Part II Preceptor Attestation.

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## AUTHORIZED USER 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 for each requested authorization:

For 35.490:Board Certification

☐ I attest that \_\_\_\_\_ has satisfactorily completed the requirements in  
Name of Proposed Authorized User  
35.490(a)(1) and has achieved a level of competency sufficient to function independently as an  
authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

☐ I attest that \_\_\_\_\_ has satisfactorily completed the 200 hours of  
Name of Proposed Authorized User  
classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised  
clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a  
level of competency sufficient to function independently as an authorized user of manual brachytherapy  
sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

☐ I attest that \_\_\_\_\_ has satisfactorily completed the 24 hours of  
Name of Proposed Authorized User  
classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy,  
has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has  
achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for  
ophthalmic use.

## Second Section

For 35.690:Board Certification

☒ I attest that Tyvis Rich has satisfactorily completed the requirements in  
Name of Proposed Authorized User  
35.690(a)(1).

OR

Training and Experience

☐ I attest that \_\_\_\_\_ has satisfactorily completed 200 hours of classroom  
Name of Proposed Authorized User  
and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical  
experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND



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## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## Preceptor Attestation (continued)

## Third Section

## For 35.690: (continued)

☒ I attest thatTyvin Rich  
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

☒ I attest thatTyvin Rich  
Name of 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 ☒ 35.600 Gamma stereotactic radiosurgery unit(s)☐ 35.600 Remote afterloader unit(s)

Name of Preceptor

Signature

Telephone Number

Date

James M. Larner, M.D.[Signature]434 924 55619/26/07

License/Permit Number/Facility Name

45-00034-30University of Virginia Gamma Knife