UNIVERSITY of VIRGINIA HEALTH SYSTEM

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 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. Larner, 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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University of Virginia Health System, PO Box 800375 • Charlottesville, VA 22908-0375
Office: (434) 924-5421 • Fax: (434) 982-3520

- 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

September 27, 2007

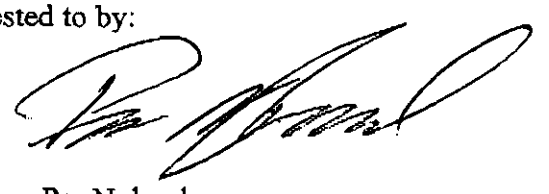
As a board-certified Swedish Physicist and Senior Product Manager for Leksell Gamma Knife Perfexion, I provided vendor-based on-site training at the University of Virginia between 23-27 September 2007. As detailed in the attached brochure, this training included:

- 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:

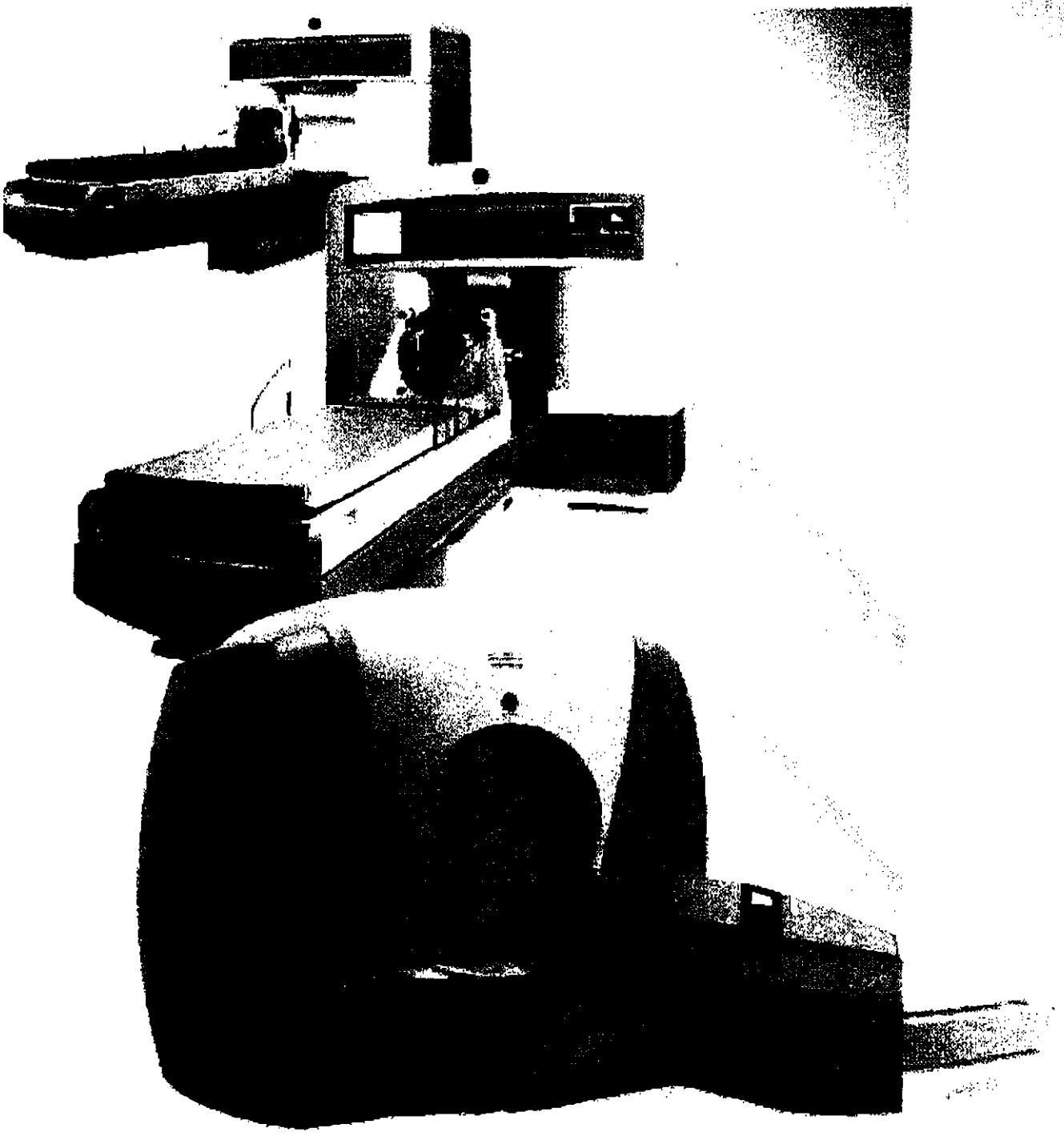


Per Nylund
Senior Product Manager, Leksell Gamma Knife
Kungstengatan 18, Box 7593
SE-103 93 Stockholm, Sweden

e-mail: Per.Nylund@Elekta.com

EDUCATION & TRAINING

Leksell Gamma Knife®



Successful system start

ELEKTA

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.

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NRC FORM 313A (AMP) (10-2006) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51]

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

Name of Proposed Authorized Medical Physicist
CARLOS H. CARBINI

Requested Authorization(s) (check all that apply)
- ☐ 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)

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. 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.

☒ 2. **Current Authorized Medical Physicist Seeking Additional Authorization for use(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 Proposed Authorized Medical Physicist**

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.

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.

☐ 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.

AND

☐ 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.

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)

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), sterotactic 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	Perfexion Specific Gamma Stereotactic Radiosurgery
Hands-on device operation			Worked with Perfexion RSO/AMP 9/17/07-Present Vendor based on-site 9/23 - 9/27/07
Safety procedures for the device use			Worked with Perfexion RSO/AMP 9/17/07-Present Vendor based on-site 9/23 - 9/27/07
Clinical use of the device			Worked with Perfexion 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 Pysicist, (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 AQUALINO, Ph.D.	45-00034-30 45-00034-26

for the following types of use:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☒ Gamma stereotactic radiosurgery unit(s) Perfexion + 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) 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 _____ 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 an AMP on a Georgia license (See 10CFR35.57(a))

OR

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	Signature	Telephone Number	Date
ALAN AQUALINO	Alan Aq	4349820152	9/27/07

License/Permit Number/Facility Name: 45-00034-30 University of Virginia Gamma Knife

NRC FORM 313A (AMP) (10-2006) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51]

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

Name of Proposed Authorized Medical Physicist

STANLEY H. BENEDICT, Ph.D.

Requested Authorization(s) (check all that apply)

- ☐ 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)

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. 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.*

☒ **2. Current Authorized Medical Physicist Seeking Additional Authorization for use(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 Proposed Authorized Medical Physicist**

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.

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.

☐ 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.

AND

☐ 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.

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), sterotactic 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	Perfexion Specific Gamma Stereotactic Radiosurgery
Hands-on device operation			Worked with Perfexion RSO/AMP 9/24/07-Present Vendor based on-site 9/26-9/27/07
Safety procedures for the device use			Worked with Perfexion RSO/AMP 9/24/07-Present Vendor based on-site 9/26-9/27/07
Clinical use of the device			Worked with Perfexion 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 Perfexion Dosimetrist 9/26-9/27/07

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 AQUALINO, Ph.D	45-00034-30 45-00034-26

for the following types of use:

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

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 (Name of Proposed Authorized Medical Physicist) has satisfactorily completed the requirements in 10 CFR 35.51(a)(1) and (a)(2).

OR

2. Education, Training, and Experience

☒ I attest that Stanley H. Benedict (Name of Proposed Authorized Medical Physicist) 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:

☒ I attest that Stanley H. Benedict (Name of Proposed Authorized Medical Physicist) has training for the types of use for which authorization 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 (Name of Proposed Authorized Medical Physicist) has achieved a level of competency sufficient to 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	Signature	Telephone Number	Date
ALAN AQUALINO	Alan Aqualino	4349820152	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	State or Territory Where Licensed
Paul W. Read, M.D./Ph.D.	Virginia

Requested Authorization(s) (check all that apply)

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

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		☐ 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	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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		

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

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)

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		☐ 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 ☐ 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*
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		

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 (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 that Paul W. Read (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, MD		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. 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	State or Territory Where Licensed
TYVIN RICH, M.D.	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**

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			
Total Hours of Training:			

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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		☐ 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	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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		
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		☐ 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 ☐ 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*
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		

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.

NRC FORM 313A (AUS) (3-2007) U.S. NUCLEAR REGULATORY COMMISSION

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 Tyvin 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 that Tyvin 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 that Tyvin 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.		434 924 5561	9/26/07

License/Permit Number/Facility Name

45-00034-30 University of Virginia Gamma Knife