NRC FORM 313A (AUS) (3-2009) 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: 3/31/2012

Name of Proposed Authorized User	State or Territory Where Licensed
Bruce McGibbon, M.D.	CT

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	UCLA Dept of Radiation Oncology	40	7/1/05 - 6/30/09
Radiation protection	Same as above	40	7/1/05 - 6/30/09
Mathematics pertaining to the use and measurement of radioactivity	Same as above	40	7/1/05 - 6/30/09
Radiation biology	Same as above	190	7/1/05 - 6/30/09
Total Hours of Training:		190	

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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:** 700	
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	**UCLA Department of Radiation Oncology Broadscope License/Authorization LA 709**	☐ Yes ☐ No	**7/1/05 - 6/30/09**
Checking survey meters for proper operation	**Same as above**	☑ Yes ☐ No	**7/1/05 - 6/30/09**
Preparing, implanting, and safely removing brachytherapy sources	**Same as above**	☑ Yes ☐ No	**7/1/05 - 6/30/09**
Maintaining running inventories of material on hand	**Same as above**	☐ Yes ☐ No	**7/1/05 - 6/30/09**
Using administrative controls to prevent a medical event involving the use of byproduct material	**Same as above**	☑ Yes ☐ No	**7/1/05 - 6/30/09**
Using emergency procedures to control byproduct material	**Same as above**	☑ Yes ☐ No	**7/1/05 - 6/30/09**

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	**Same as above**	

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User
Michael Steinberg, MD, Chairman UCLA Dept. of Rad. Onc.	**LA709**

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
Yale-New Haven GammaKnife Cener

Total Hours of Experience: 40

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	UPitt GammaKnife Training Center	☑ Yes ☐ No	May 11-15, 2009
Preparing treatment plans and calculating treatment doses and times	UPitt GammaKnife Training Center	☑ Yes ☐ No	May 11-15, 2009
Using administrative controls to prevent a medical event involving the use of byproduct material	UPitt GammaKnife Training Center	☑ Yes ☐ No	May 11-15, 2009
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	UPitt GammaKnife Training Center	☑ Yes ☐ No	May 11-15, 2009
Checking and using survey meters	UPitt GammaKnife Training Center	☑ Yes ☐ No	May 11-15, 2009
Selecting the proper dose and how it is to be administered	UPitt GammaKnife Training Center	☑ Yes ☐ No	May 11-15, 2009

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			**UPitt GammaKnife Training Center** **May 11-15, 2009**
Safety procedures for the device use			**UPitt GammaKnife Training Center** **May 11-15, 2009**
Clinical use of the device			**UPitt GammaKnife Training Center** **May 11-15, 2009**

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
Jonathan Knisely, MD **Lic 06-00819-03**	**YNHH GammaKnife Ctr. NRC Lic 06-30445-01**

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.

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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

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 _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

☑ I attest that Bruce McGibbon, MD 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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Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

|✔| I attest that **Bruce McGibbon, MD** (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 **Bruce McGibbon, MD** (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
Jonathan Knisely, MD		**203-785-2960**	19NOV09
License/Permit Number/Facility Name **YNHH NRC Lic Nos: 06-00819-03 & 06-30445-01**			