

Q-4
MS-16

MIDSTATE MEDICAL CENTER

435 Lewis Avenue, Meriden, CT 06451

To: US Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

October 27, 2011

Re: Amendment request; NRC Materials License No. 06-05686-02

03001257

Dear Sir or Madam:

The following letter serves to present additional information requested by your office in order to proceed with an HDR license amendment for our institution

Should you have any questions or desire additional information for this licensing action, please contact Mrs. Leticia Morrissey, MS, Medical Physicist, at (203) 694-8433. Thank you for your time and efforts.

Respectfully submitted,



Cindy Russo
Senior Vice President of Operations

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

Allan S. Kratzer, MD

State or Territory Where Licensed

Connecticut

Requested

35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)

Authorization(s)

35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s)

(check all that apply)

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	Residency Program Harvard Joint Center for Radiation Therapy 50 Binney Street Boston, MA	165	July 1, 1986 through June 30, 1989
Radiation protection	Residency Program	75	as above
Mathematics pertaining to the use and measurement of radioactivity	Residency Program	50	as above
Radiation biology	Residency Program	50	as above

Total Hours of Training: 340

NRC FORM 313A (AUS)
(3-2008)

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: minimum of 500	
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	Residency Program Harvard Joint Center for Radiation Therapy 50 Binney Street Boston, MA	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	July 1, 1986 through June 30, 1989
Checking survey meters for proper operation	Residency Program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	as above
Preparing, implanting, and safely removing brachytherapy sources	Residency Program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	as above
Maintaining running inventories of material on hand	Residency Program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	as above
Using administrative controls to prevent a medical event involving the use of byproduct material	Residency Program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	as above
Using emergency procedures to control byproduct material	Residency Program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	as above

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: <input checked="" 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	Residency Program Harvard Joint Center for Radiation Therapy 50 Binney St Boston, MA	July 1, 1986 through June 30, 1989

Supervising Individual Jay Harris, MD	License/Permit Number listing supervising individual as an Authorized User
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NRC FORM 313A (AUS)
(2-2009)

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 70 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	Univ. of CT Health Ctr. (06-13022-02)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	10/13/11
Preparing treatment plans and calculating treatment doses and times	Nucletron Headquarters, Maryland Hartford Hospital (06-00253-04)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6/22/11 6/16,6/17,6/20 6/27,6/28,6/29 7/5,7/7, 7/18/11
Using administrative controls to prevent a medical event involving the use of byproduct material	Nucletron Headquarters, Maryland MidState Medical Ctr.(06-05688-02) Univ. of CT Health Ctr. (06-13022-02) Hartford Hospital (06-00253-04)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6/22/11 3/8/11 10/13/11 7/5,7/7,7/11, 7/12,7/14,7/19
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	MidState Medical Ctr.(06-05688-02) Nucletron Headquarters, Maryland Univ. of CT Health Ctr. (06-13022-02) Hartford Hospital (06-00253-04)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	3/8/11 6/22/11 10/13/11 7/5/11
Checking and using survey meters	MidState Medical Ctr.(06-05688-02) Univ. of CT Health Ctr. (06-13022-02)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/14/11, 8/11/11 10/13/11
Selecting the proper dose and how it is to be administered	Hartford Hospital (06-00253-04) Nucletron Headquarters, Maryland	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6/16,6/17,6/20 6/27,6/29,7/5, 7/7,7/11,7/19 6/22/11

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 35.680 (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: <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	Nucletron Headquarters(6/22/11) Hartford Hospital (6/29,7/5/11) MidState Med Ctr (3/8,4/29/11) Univ.of CT Health Ctr (10/13/11)		
Safety procedures for the device use	Nucletron Headquarters(6/22/11) Hartford Hospital (6/29,7/5/11) MidState Med Ctr (3/8,4/29/11) Univ. of CT Health Ctr (10/13/11)		
Clinical use of the device	Hartford Hospital (6/28/11, 6/29/11,6/30/11,7/5/11,7/7/11, 7/11/11,7/12/11,7/14/11,7/19/11) Midstate Med Ctr (4/29/11) PLEASE SEE DR.KRATZER'S ATTACHED LETTER FOR DETAILS		
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.) Timothy S. Boyd, MD		License/Permit Number listing supervising individual as an Authorized User 06-00253-04 - Hartford Hospital	
Authorized for the following types of use: <input checked="" type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> 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 Allan S. Kratzer 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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

I attest that Allan S. Kratzer, MD 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 Allan S. Kratzer, MD 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 35.600 Gamma stereotactic radiosurgery unit(s)

35.600 Remote afterloader unit(s)

Name of Preceptor Timothy S. Boyd	Signature <i>Timothy S. Boyd</i>	Telephone Number (860) 545-2803	Date 10/25/2011
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License/Permit Number/Facility Name
06-00253-04 - Hartford Hospital

HARTFORD HOSPITAL

Helen & Harry Gray Cancer Center
Hartford, CT 06102 Tel 860-545-2803

To: US Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

October 25, 2011

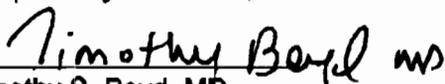
Re: Training and Experience of Allan S. Kratzer, MD

Dear Sir or Madam:

This letter serves as my confirmation of the Training and Experience as detailed by Allan S. Kratzer, MD, radiation oncologist. Dr. Kratzer is seeking to become an HDR authorized user on the Radioactive Materials License of Midstate Medical Center in Meriden, CT.

Should you have any questions or desire additional information for this licensing action, please contact me at (860) 545-2803. Thank you for your time and efforts.

Respectfully submitted,


Timothy S. Boyd, MD
Helen & Harry Gray Cancer Center