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October 25, 2007

NM561

U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

03037051

RECEIVED
REGION 1

2007 NOV - 1 PM 1:31

Re: License No. 37-31098-01

Dear Sir or Madam:

Please amend the above referenced license as follows:

- Remove Lydia Komarnicky as an authorized user.
- Add Curt Heese, M.D., as an HDR authorized user for high dose rate remote after-loaded brachytherapy (HDR) permitted under 10 CFR 35.600. NRC Form 313 is attached for Dr. Heese.
- Add Usha Babaria, M.D., as an HDR authorized user for high dose rate remote after-loaded brachytherapy (HDR) permitted under 10 CFR 35.600. Dr. Babaria is listed on NRC License No. 29-12253-01, Amendment No. 34. She is also currently an authorized user for HDR on NRC broad scope license no. 37-00467-36.

If you need any additional information or have any questions regarding this request you may contact our radiation safety officer, Kent Lambert (215-762-8768; kent.lambert@drexel.edu). If I can be of assistance, do not hesitate to contact me.

Sincerely,


Barry Hamp

141268

NMSS/RGN1 MATERIALS-002

NRC FORM 313A (AUS) (3-2007)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0121 EXPIRES: 10/31/2008
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]		

Name of Proposed Authorized User Curt Heese	State or Territory Where Licensed PA
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Requested Authorization(s) (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 type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s)
<input checked="" 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	Hahnemann Radiation Oncology Drexel University	100	07/01/2003 - 06/30/2007
Radiation protection	Hahnemann Radiation Oncology Drexel University	10	07/01/2003 - 06/30/2007
Mathematics pertaining to the use and measurement of radioactivity	Hahnemann Radiation Oncology Drexel University	40	07/01/2003 - 06/30/2007
Radiation biology	Hahnemann Radiation Oncology Drexel University	100	07/01/2003 - 06/30/2007
Total Hours of Training:		250	

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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*
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	

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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: 600	
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	Hahnemann Hospital	<input type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2003 - 06/30/2007
Preparing treatment plans and calculating treatment doses and times	Hahnemann Hospital	<input type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2003 - 06/30/2007
Using administrative controls to prevent a medical event involving the use of byproduct material	Hahnemann Hospital	<input type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2003 - 06/30/2007
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	Hahnemann Hospital	<input type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2003 - 06/30/2007
Checking and using survey meters	Hahnemann Hospital	<input type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2003 - 06/30/2007
Selecting the proper dose and how it is to be administered	Hahnemann Hospital	<input type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2003 - 06/30/2007

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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: <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	37-00467-36	07/01/2003 to 06/30/2007
Supervising Individual Lydia Komarnicky, M.D.	License/Permit Number listing supervising individual as an Authorized User 37-00467-36	

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	07/01/2003 to 06/30/2007	N/A	N/A
Safety procedures for the device use	07/01/2003 to 06/30/2007	N/A	N/A
Clinical use of the device	07/01/2003 to 06/30/2007	N/A	N/A
Supervising Individual. <i>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.)</i> Lydia Komarnicky, M.D.		License/Permit Number listing supervising individual as an Authorized User 37-00467-36	

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 ~~_____~~ Curie Heese, M.D. has satisfactorily completed the requirements in
Name of Proposed Authorized User
~~35.690(a)(1).~~ *Corrected per e-mail from L.K.*

OR

Training and Experience

I attest that Curie Heese, M.D. 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 Curtis Heese, M.D. *CH* 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 Curtis Heese, M.D. *CH* 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 Lydia Kormamicky, M.D.	Signature <i>LK</i>	Telephone Number 215-762-4984	Date 8/31/07
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License/Permit Number/Facility Name
37-00467-36 Hahnemann University Hospital

This is to acknowledge the receipt of your letter/application dated

10/25/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 37-31092-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 141268.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.