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November 21, 2011

United States Nuclear Regulatory Commission
Region IV
612 East Lamar Blvd. Suite 400
Arlington, Texas 76011
Attn: Lizette Roldan-Otero, Ph.D., Health Physicist

Subject: License Amendment for Billings Clinic NRC License # 25-01051-01

Dr. Roldan-Otero:

Please accept a corrected copy of NRC form 313A (AUS) for Dr. Michael Hasselle. I incorrectly typed 250 hours under item 3 training and experience for 10 CFR 35.490. The ACGME requirements for radiation oncology require a minimum of 500 hours of supervised work and clinical experience. I did confirm at the time Dr. Hasselle had completed the required 500+ hours of experience. I apologize for the typographical error during the original submission of the original document.

We also wish to remove Andrew Schneider, Ph.D., as an authorized user for HDR.

Thank you for your assistance with this request. If you require additional information please contact me at 406-672-6756.

Sincerely,

Chris Fitz
Radiation Safety Officer
Billings Clinic

**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

Michael D. Hasselle, M.D.

Illinois, Montana

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

- 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	University of Chicago/University of Illinois at Chicago combined residency program	150	07/01/2007 - 06/30/2011
Radiation protection	University of Chicago/University of Illinois at Chicago combined residency program	100	07/01/2007 - 06/30/2011
Mathematics pertaining to the use and measurement of radioactivity	University of Chicago/University of Illinois at Chicago combined residency program	150	07/01/2007 - 06/30/2011
Radiation biology	University of Chicago/University of Illinois at Chicago combined residency program	150	07/01/2007 - 06/30/2011
Total Hours of Training:		550	

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: 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	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2007-06/30/2011
Checking survey meters for proper operation	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" 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 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	University of Chicago/University of Illinois at Chicago combined residency program (IL-016778-02) Memorial Sloan Kettering Brachytherapy Fellowship (1 month) New York City, 75-2968-01	07/01/2007-06/30/2011 02/01/10-02/28/10
Supervising Individual Steven Chumura, U of C, Michael Zelefsky, MSK		License/Permit Number listing supervising individual as an Authorized User IL-01678-02, New York 75-2968-01

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: 500	
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	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2007 - 06/30/2011
Preparing treatment plans and calculating treatment doses and times	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2007 - 06/30/2011
Using administrative controls to prevent a medical event involving the use of byproduct material	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2007 - 06/30/2011
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2007 - 06/30/2011
Checking and using survey meters	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2007 - 06/30/2011
Selecting the proper dose and how it is to be administered	University of Chicago/University of Illinois at Chicago combined residency program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2007 - 06/30/2011

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:	University of Chicago/University of Illinois at Chicago combined residency program (IL-01678-02)	07/01/2007 - 06/30/2011
<input checked="" type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME		
<input type="checkbox"/> Royal College of Physicians and Surgeons of Canada	Memorial Sloan Kettering Brachytherapy Fellowship (1 month) New York City, 75-2968-01	02/01/2010 - 02/28/2010
<input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	
Steven Chmura, U of C, M. Zelefsky, MSK	IL-01678-02, New York 75-2968-01	

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	U of Chicago/U of Illinois at Chicago combined residency program (07/01/07-06/30/11) MSK 2/1-2/28/10		
Safety procedures for the device use	U of Chicago/U of Illinois at Chicago combined residency program (07/01/07-06/30/11) MSK 2/1-2/28/10		
Clinical use of the device	U of Chicago/U of Illinois at Chicago combined residency program (07/01/07-06/30/11) MSK 2/1-2/28/10		
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		
Steven Chmura, U of C, Michael Zelefsky, MSK	IL-01678-02, New York 75-2968-01		

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 Michael D. Hasselle

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 Michael D. Hasselle

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 Michael D. Hasselle 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

Name of Proposed Authorized User

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

AND

Fourth Section

☒ I attest that Michael D. Hasselle has achieved a level of competency sufficient to achieve a level of competency sufficient to function independently as an authorized user for:

Name of Proposed Authorized User

☒ 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)

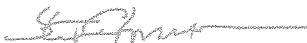
☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

☒ 35.600 Remote afterloader unit(s)

Name of Preceptor

Steven J. Chmura, MD, Ph.D

Signature



Telephone Number

773-702-0817

Date

8/5/2011

License/Permit Number/Facility Name

IL-01678-02 University Of Chicago

NOV 28 2011

DATE

This is to acknowledge the receipt of your letter/application dated NOV 21 2011, and to inform you that the initial processing, which includes an administrative review, has been performed.

☒ There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify other omissions or require additional information.

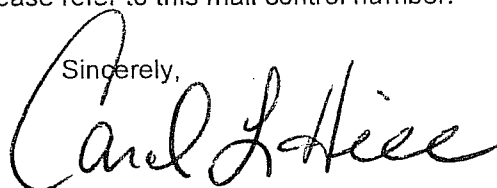
☐ Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

☐ 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** No 5 7 6 4 4 0.
When calling to inquire about this action, please refer to this mail control number.
You may call me at (817) 860-8103.

Sincerely,



Licensing Assistant

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM LTS

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date:
Fee Comments: CODE 23
Decom Fin Assur Req'd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: BILLINGS CLINIC
Received Date: 11/28/2011
Docket Number: 3002389
Mail Control Number: 576440
License Number: 25-01051-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

Carol L. Heie
11/29/11

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____