



Mercy Hospital

Department Nuclear Medicine
1235 E. Cherokee
Springfield, MO 65804
phone 417-820-2865
fax 417-820-7865
www.mercy.net

08/08/2012

Materials Licensing
US NRC Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352

ATTN License reviewer:

This letter is a request for the following amendments to license # 24-00866-02 and to notify the NRC of our HDR training schedule.

We are requesting that Kimberly M. Creach M.D. be added to our license for 35.300, 35.400 and 35.600 (HDR) use. She has provided me a copy of a preceptor form signed by Dr Perry Grigsby from Washington University that appears to be a combination of NRC forms 313A(AUT) and 313A(AUS). This form appears to document all of the required components of the training and experience required to list her for these uses. I have provided a copy of this document for your review. I have also provided a copy of her certificate from Washington University documenting the completion of her 4 year residency training in Radiation Oncology.

I have also obtained a letter from Susan Langhorst, Ph.D. which documents the current Authorized User status of Dr. Perry Grigsby as well as the other supervising individuals listed in section f of the preceptor form. Mrs. Langhorst serves as the Radiation Safety Officer at Washington University which holds an NRC Broad Scope license. (NRC license number 24-00167-11)

I would also like to add Jesse Whitlock, M.S. to condition 15 of our license as an individual who is authorized to perform tests for leakage and/or contamination. Jesse has a Masters degree in Nuclear Engineering with a Medical Physics emphasis from the University of Missouri and has been working under my supervision as a full time Medical Physicist since 2006. He has performed leak testing under my supervision on at least 10 occasions since that time and has read and is familiar with section 8.46 and appendix Q of NUREG 1556 vol. 9, Rev. 2. As RSO of this license, I can attest to the training and competence of Jesse Whitlock to perform these functions independently for our license.

I also wanted to notify the NRC as to the vendor provided training schedule that we have planned for our HDR program. The current plan is have the Physician from Penrose Hospital in Colorado come to our campus to provide clinical case training instead of the original plan of our Physician(s) traveling to Penrose. In addition to the clinical case training, there will also be a re-training on the emergency procedures provided by the Varian F.S.E. as well as applications training provided by a Varian applications specialist. I have provided a copy of the training schedule for your review. This plan will allow training in emergency/safety procedures, device operation and clinical use to be delivered contiguously for all required staff members.

If you have any questions regarding this request or if you require additional information please contact me at (417) 820-7704.

Sincerely,



Nick Lannutti, MS
Radiation Safety Officer
Department of Nuclear Medicine
St Johns Hospital-Springfield

Enclosure:

- WU Form for NRC 313A for Kimberly Creach, M.D.
- Certificate for Radiation Oncology residency training for Dr Kimberly Creach, M.D.
- Letter from Susan Langhorst, Ph.D. documenting AU status of preceptor
- Varian HDR training Schedule

Cc Linda Earnest, Administration
Alan Burns, Radiation Oncology
Mike Barnes, Nuclear Medicine

WU FORM for NRC 313A

Washington University & Medical Center

**MEDICAL USE TRAINING AND EXPERIENCE
RADIATION ONCOLOGY RESIDENT PHYSICIAN**

Name of Proposed Authorized User:

Kimberly M Creach

State or Territory Where Licensed:

Missouri

Request Authorization for following Use Types:

35.300 Use of unsealed byproduct material for which a written directive is required

35.400 Manual brachytherapy sources

35.600 Remote afterloader unit(s)

Training and Experience for Proposed Authorized User

a. Formal Training Program for 35.390, 35.490 & 35.690

Residency Program in Radiation Oncology Program ID 4302811054	Washington Univ. Med. Center, NRC License No. 24-00167-11	7/1/2008- 6/30/2012	Accreditation Council for Graduate Medical Education
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b. Classroom and Laboratory Training for 35.390, 35.490 & 35.690

Description of Training	Location of Training	Clock Hours	Dates of Training
Radiation physics and instrumentation	Washington Univ. Med. Center, NRC License No. 24-00167-11	80	7/1/2008- 6/30/2012
Radiation protection	"	32	7/1/2008- 6/30/2012
Mathematics pertaining to the use and measurement of radioactivity	"	12	7/1/2008- 6/30/2012
Radiation biology	"	80	7/1/2008- 6/30/2012
Chemistry of Byproduct Material for Medical Use	"	10	7/1/2008- 6/30/2010

Total Hours of Classroom and Laboratory Training: 214 hours

WU FORM for NRC 313A Washington University & Medical Center

**MEDICAL USE TRAINING AND EXPERIENCE
RADIATION ONCOLOGY RESIDENT PHYSICIAN [cont.]**

Proposed Authorized User: Kimberly M. Creach Page 2 of 5

d. Supervised Work Experience for 10 CFR 35.390, 35.490 & 35.690

Description of Experience Must Include:	Location of Experience/ License or Permit Number of Facility	Name of Supervising Individual(s)	Dates of Training
Ordering, receiving, & unpacking radioactive materials safely & performing the related radiation surveys	Washington Univ. Med. Center, NRC License No. 24-00167-11	See Section f.	7/1/2008-6/30/2012
Performing QC procedures on instruments used to determine the activity of dosages & performing checks for proper operation of survey meters	"	"	"
Calculating, measuring, & safely preparing patient or human research subject dosages	"	"	"
Administering dosages of radioactive drugs to patients or human research subjects	"	"	"
Preparing treatment plans & calculating treatment doses & times	"	"	"
Preparing, implanting, and safely removing brachytherapy sources	"	"	"
Selecting the proper dose & how it is to be administered	"	"	"
Maintaining running inventories of material on hand	"	"	"
Using administrative controls to prevent a medical event involving the use of unsealed & sealed byproduct material	"	"	"
Using/implementing emergency procedures to safely contain & properly decontaminate spilled byproduct material, to safely control sealed byproduct material, & be followed in the event of the abnormal operation of the medical unit or console	"	"	"
Reviewing full calibration measurements & periodic spot-checks	"	"	"

WU FORM for NRC 313A Washington University & Medical Center

**MEDICAL USE TRAINING AND EXPERIENCE
RADIATION ONCOLOGY RESIDENT PHYSICIAN [cont.]**

Proposed Authorized User: **Kimberly M. Greach** Page 3 of 5

e. Supervised Clinical Experience for 10 CFR 35.390

Description of Experience	No. of Cases	Location of Experience/ License or Permit Number of Facility	Name of Supervising Individual(s)	Dates of Training
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) - minimum of 3 cases required	23	Washington Univ. Med. Center, NRC License No. 24-00167-11	See Section f.	7/1/2008-6/30/2012
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required - minimum of 3 cases required in total number of parenteral administrations	10	"	"	
Parenteral administration of any other radionuclide for which a written directive is required	1	"	"	

Total Hours of Supervised Work & Clinical Experience: > 500 hours

WU FORM for NRC 313A

Washington University & Medical Center

**MEDICAL USE TRAINING AND EXPERIENCE
RADIATION ONCOLOGY RESIDENT PHYSICIAN [cont.]**

Proposed Authorized User:

Page 4 of 5

f. Supervising Individuals for 35.300, 35.400 & 35.600

Name	Location of Authorization/ License Number of Facility	Authorized in Part 35	Supervisor meets requirements of Part 35
Jeffrey D. Bradley, MD	Washington Univ. Med. Center, NRC License No. 24-00167-11	300, 400, 600 (HDR)	390, 490, 690 (HDR)
Perry W. Grigsby, MD, MBA	"	300, 400, 600 (HDR)	390, 490, 690 (HDR)
David B. Mansur, MD	"	300, 400, 600 (HDR, GK), 1000 (PGK)	390, 490, 690 (HDR, GK, PGK)
Jeff M. Michalski, MD, MBA	"	300, 400, 600 (HDR), 1000 (SIR- Spheres)	390, 490, 690 (HDR)
Robert J. Myerson, MD, PhD	"	300, 400, 600 (HDR), 1000 (SIR- Spheres)	390, 490, 690 (HDR)
Parag J. Parikh, MD	"	300, 400, 600 (HDR), 1000 (SIR- Spheres)	390, 490, 690 (HDR)
Joseph R. Simpson, MD, PhD	"	300, 400, 600 (HDR, GK), 1000 (PGK)	390, 490, 690 (HDR, GK, PGK)
Marie E. Taylor, MD	"	300, 400, 600 (HDR)	390, 490, 690 (HDR)
Wade L. Thorstad, MD	"	300, 400, 600 (HDR)	390, 490, 690 (HDR)
Imran Zoberi, MD	"	300, 400, 600 (HDR, GK), 1000 (SIR- Spheres, PGK)	390, 490, 690 (HDR, GK, PGK)

* HDR=High Dose Rate Remote Afterloader; GK=Gamma Knife; PGK=Perfection Gamma Knife

WU FORM for NRC 313A

Washington University & Medical Center

**MEDICAL USE TRAINING AND EXPERIENCE
RADIATION ONCOLOGY RESIDENT PHYSICIAN [cont.]**

Proposed Authorized User:

Page 5 of 5

PRECEPTOR ATTESTATION
(see Section I. for Preceptor Qualifications)

I attest that **Kimberly M. Creach** has met all the requirements listed below:

- Has satisfactorily completed the requirements in Part 35.390, 490 and 690.
- Meets the requirements in 35.390(b)(1)(ii)(G) for all radiopharmaceuticals requiring written directive and 35.690(c) for HDR.
- Has achieved a level of competency sufficient to function independently as an authorized user for 300, 400 and 600 (HDR) uses.

Name of Preceptor	Signature	Date
Perry W. Gingsberg	<i>P. Gingsberg</i>	7-MAR-2012

Facility Name/Address	NRC License No.
Washington University in St. Louis 660 S. Euclid Avenue Campus Box 8053 St. Louis, MO 63100-1093	24-00167-11

NO. 116 P. 1

Department of Radiation Oncology

Washington University

And

Barnes-Jewish Hospital

St. Louis, Missouri



Does hereby acknowledge that

Kimberly M. Creach, MD

has satisfactorily completed 4 years of approved
residency program in Radiation Oncology

July 1, 2008 to June 30, 2012

BARNES-JEWISH®
Hospital
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 Washington
University in St. Louis
SCHOOL OF MEDICINE

Dennis E. Hallahan

Dennis E Hallahan, MD, Chairman and Program Director
Department of Radiation Oncology

Jeff M. Michalski

Jeff M Michalski, MD, Vice Chair and Clinical Director
Department of Radiation Oncology

Environmental Health & Safety

Radiation Safety Office

August 3, 2012

TO: Whom It May Concern

FROM: Susan M. Langhorst, Ph.D., CHP
Radiation Safety Officer



SUBJECT: Confirmation of Authorization for Medical Use of Radioactive Materials

Washington University in St. Louis holds a Nuclear Regulatory Commission Broad Scope Type A medical license (NRC License No. 24-00167-11). Our license covers medical use of licensed material used at Washington University in St. Louis, Barnes-Jewish Hospital, and St. Louis Children's Hospital facilities. I confirm the physicians listed below are currently approved under NRC License No. 24-00167-11 as Authorized Users for the medical uses identified below.

Physician Name	10 CFR 35 Approved Use						
	100	200	300	400	600 HDR ¹	1000 GKP ²	1000 μ Spheres ³
Bradley, Jeffrey D.			✓	✓	✓		
Grigsby, Perry W.			✓	✓	✓		✓
Mansur, David B. (removed 1/10/2012)			✓	✓	✓	✓	
Michalski, Jeff M.			✓	✓	✓		
Myerson, Robert J.			✓	✓	✓		✓
Parikh, Parag J.			✓	✓	✓		✓
Simpson, Joseph R.			✓	✓	✓	✓	
Taylor, Marie E.			✓	✓	✓		
Thorstad, Wade L.	✓	✓	✓	✓	✓	✓	
Zoberi, Imran			✓	✓	✓	✓	✓

¹ HDR: High Dose Remote Afterloader

² GKP: Gamma Knife – Perfexion

³ μ Spheres: Y-90 SIR-Spheres & Y-90 TheraSpheres

Please contact me at langhors@wustl.edu or (314) 362-2988 if you have questions concerning this information.

Cc: Medical Use file

Varian HDR Brachytherapy Schedule

IRIDIUM 912 Source delivery schedule:

- Ship date August 3, 2012
- Estimated Delivery Date, August 7, 2012

Monday August 13, 2013: David Branstetter, Field Service Engineer:

- VariSource iX source installation, emergency training and full acceptance
- David will arrive around 10:00 AM

Tuesday – Thursday August 28-30 on site training: Mike Mariscal, Varian BrachyTherapy applications specialist

- BrachyVision refresher
- VariSource iX on-site applications training
- Mike will arrive on Monday 8/27/12
- A SAMPLE of the training schedule will be forwarded to Rad Onc staff. We will meet with Mike first thing 8/28 to customize for our needs.

Preceptor On-site Training for Radiation Oncology Staff:

- Travel from Colorado Springs, CO to SFG, MO – Saturday, September 8, 2012.
- On-site didactic – Sunday, September 9, 2012
- Preceptor of first cases, Monday, September 10, 2012

Contact information:

Moni Samford, Varian Brachytherapy Project Manager - 615 790 9817 (phone), 615 415 7626 (mobile)

monica.samford@varian.com

David Branstetter, Field Service Engineer, 573-465-2779 (mobile),

david.branstetter@varian.com

Mike Mariscal, Apps Specialist, 434 977 8495 ext 250 or 434 227 0797 (mobile),

Michael.Mariscal@varian.com

Preceptors -Penrose Hospital Staff – Physican – Anuj V. Peddada, M.D.. (719) 776-5281

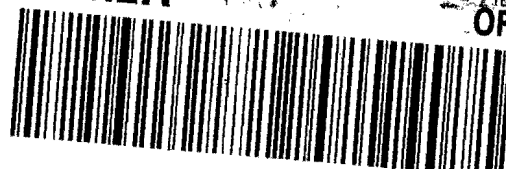
Physicist –Gerald White, GeraldWhite@Centura.Org - (719) 776-2513



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Date 8-9-2012 FedEx Tracking Number 800349159587

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Company SISTER OF MERCY HEALTH SYSTEM

Address 1235 E CHEROKEE ST Dept./Floor/Suite/Room

City SPRINGFIELD State MO ZIP 65804-2203

2 Your Internal Billing Reference

3 To Recipient's Name Materials Licensing Phone 301 415-7000

Company USNRC Region III

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<input type="checkbox"/> FedEx Priority Overnight Next business morning. *Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.	<input type="checkbox"/> FedEx 2Day Second business afternoon. *Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.
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