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BON SECOURS
DEPAUL MEDICAL CENTER
Bon Secours Health System

United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

VIA FACSIMILE: 610-337-5269

November 13, 2006

03003302

Subject: BON SECOURS – DEPAUL MEDICAL CENTER LICENSE AMENDMENT (License 45-00986-01)

To Whom It May Concern:

Please make the following changes to the materials license for Bon Secours DePaul Medical Center (license 45-00986-01):

- Please add Biral Amin, M.D. Material use: 35.300, 35.400, Ir-192 for uses in a High Dose Remote Afterloader Unit; Depleted Uranium
- Please remove Bernard Tisdale, M.D.
- Please remove Adedamola Omogbehin, M.D.
- Please remove Denise Renee Gooch, M.D.
- Remove Felix A. Hughes, III, M.D.

Documentation regarding Dr. Amin is attached. Should you need additional information or action from us, please contact Kristi Sink, Director Oncology at 757-889-5945.

Thank you for your assistance in this matter.

Sincerely,

Kristi Sink
Director Oncology

Copy to: Daniel Duggan, Executive Vice President/Administrator
Christopher Sinesi, M.D., Medical Director Radiation Oncology
Robert T. Mariano, M.D., Radiation Safety Officer

139741
NMSS/RGNI MATERIALS-002

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11/13/2006

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008

PART I - TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

BREAL Amin, 10CFR 35.300 10CFR 35.400 10CFR 35.600

2. For Physicians, Podiatrists, Dentists, Pharmacists - State or Territory Where Licensed

Virginia

3. CERTIFICATION

a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)

b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.398(d)(2); 35.590(c); or 35.690(c).

c. Provide completed Part II Preceptor Attestation, items 11a through 11d.

Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

a. Provide a copy of the license or broadscope permit listing the current authorization and (b) or (c)

b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).

c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	NY Methodist Hosp 506 6 th St. Brooklyn, NY 11215	200 hr	July 2001 June 2005
Radiation Protection	↓	200 hrs	July 2001 June 2005
Mathematics Pertaining to the Use and Measurement of Radioactivity		200 hr	July 2001 June 2005
Radiation Biology		300 hr	July 2001 June 2005
Chemistry of Byproduct Material for Medical Use		100 hr	July 2001 June 2005
OTHER			

NRC FORM 313A (10-2015) MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) U.S. NUCLEAR REGULATORY COMMISSION

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Review full calibration measurements and periodic spot checks for remote afterloaders, checking and	DR. Selim & Dr. Rafla	N4 Methodist Hospital BK140 M.	July 2001 June 2005
Prepare treatment plans, calculate treatment doses & times, select proper dose and how it is to be administered for afterloaders	DR. Selim & DR. Rafla		
Using administrative controls to prevent a medical event involving the use of byproduct material (H ²² manual brachytherapy and unsealed sources)	DR. Selim & DR. Rafla		
Implementing emergency procedures to be followed in the event of an abnormal operation of the medical unit or console of an afterloader	DR. Selim & DR. Rafla		
Ordering, receiving and unpacking radioactive materials safely and performing radiation surveys for manual brachytherapy sources and unsealed	DR. Selim & DR. Rafla		
Preparing, implanting and removing brachytherapy sources, maintaining running inventories of material on hand	DR. Selim & DR. Rafla		
Using emergency procedures to control byproduct material using procedures to contain spilled byproduct material and decontamination procedures	DR. Selim & DR. Rafla		
Performing QC procedures on instruments used to determine the activity, or dosage, calculating measuring and preparing patient dosages	DR. Selim & DR. Rafla		

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
I-131	Therapy < 33mCi	5	DR. Selim & DR. Rafla	N4 Methodist Hospital	7/01-6/05
I-131	Therapy > 33mCi	5			7/01-6/05
I-125	Seed implantation	50			
Au-198	Seed implantation unsealed	2			
P-32	intracavitary unsealed	3			
Sm-153	intravenous	5			
Cs-137	manual brachytherapy	730			
Ir-192	Manual brachytherapy	750			

NRC FORM 313A
(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL - IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each):

A. Name of Supervisor

Hosny Selim, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.390(a) and (b)(1)(ii)(G)
for medical uses in Part 35, Section(s) _____

D. Address

E. Materials License Number

91-2842-01

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 390; 490, 690
as documented in section(s) 5 & 6 of this form.

11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for authorized user
 N/A types of use, as documented in section(s) 5 through 6 of this form.

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); OR

has achieved a level of competency sufficient to function independently as an authorized
USER for 35.390, 35.490, 35.690 uses (or units); OR

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; OR

N/A

11d.

I am an Authorized Nuclear Pharmacist; OR I am a Radiation Safety Officer; OR

I meet the requirements of _____ section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor AU or AMP

for the following byproduct material uses (or units): _____

A. Address

506 6th St
Brooklyn, NY 11215

B. Materials License Number

91-2842-01

C. NAME OF PRECEPTOR (print clearly)

Hosny Selim, MD

D. SIGNATURE - PRECEPTOR

[Signature]

E. DATE

11/14/06

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training*	Location and Dates
Remote Afterloaders	supervised and didactic	July 2001 - June 2005
Use of manual sources. use of unsealed product material		

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
Radiation Oncology MD	NY Methodist Hospital Brooklyn NY. 91-2842-01	July 2001 - June 2005	ACGME

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
 N/A of _____ the RSO for License No. _____

9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____
 N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____
 N/A under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

[CLICK HERE AND TYPE COMPANY NAME]

FACSIMILE TRANSMITTAL SHEET

TO:	NRC Ammendments	FROM:	Kristi Sink, Director Oncology
COMPANY:	NRC	DATE:	11/13/2006
FAX NUMBER:	610-337-5269	TOTAL NO. OF PAGES INCLUDING COVER:	[Click here and type number of pages]
PHONE NUMBER:		SENDER'S PHONE NUMBER	757-889-5945
RE:	NRC Ammendment for Bon Secours DePaul Medical Center (License 45- 00986-01)	SENDERS FAX NUMBER	757-889-4229

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RECYCLE

NOTES/COMMENTS:

Please find attached a request for the amendment of the license at Bon Secours DePaul Medical Center. The original has been sent via regular United States Postal Service mail. Thank you.

[CLICK HERE AND TYPE RETURN ADDRESS]

* * * Transmission Result Report (MemoryTX) (Nov.13. 2006 1:56PM) * * *

1)
2)

Date/Time: Nov.13. 2006 1:54PM

File No. Mode	Destination	Pg (s)	Result	Page Not Sent
0771 Memory TX	7-49145-16103375269	P. 6	OK	

Reason for error

E.1) Hang up or line fail
E.3) No answer

E.2) Busy
E.4) No facsimile connection

[CLICK HERE AND TYPE COMPANY NAME]

FACSIMILE TRANSMITTAL SHEET

TO: NRC Amendments	FROM: Kristi Sink, Director Oncology
COMPANY: NRC	DATE: 11/13/2006
FAX NUMBER: 610-337-5269	ROYAL NO. OF PAGES INCLUDING COVER: [Click here and type number of pages]
PHONE NUMBER:	SENDER'S PHONE NUMBER: 757-889-5945
RE: NRC Amendment for Bon Secours DePaul Medical Center (License 45-00986-01)	SENDER'S FAX NUMBER: 757-889-4229

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NOTES/COMMENTS:

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[CLICK HERE AND TYPE RETURN ADDRESS]

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

11/13/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 45-60986-01 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 139741.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.