



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

SEP 01 2011

Jacek G. Wierzbicki Ph.D.
Radiation Safety Officer
St. Mary's of Michigan Medical Center
800 S. Washington Street
Saginaw, MI 48601

Dear Dr. Wierzbicki:

This refers to your letter dated June 10, 2011, regarding the proposed addition of Mr. Bijoyananda Adhikary, M.S. to your license as an Authorized Medical Physicist (AMP) for the use of iridium-192 in a high dose rate remote afterloading brachytherapy device (HDR).

There were several discrepancies in your letter and in Mr. Adhikary's 313a (AMP) forms, which are noted in the "marked-up" copy enclosed.

In particular, note that we will need to have a copy of Mr. Adhikary's master's degree diploma provided that shows the date and degree conferred, as the letter from Dr. Burmeister will not suffice as proof of receipt of the degree. Please submit this diploma copy.

Your letter dated June 10, 2011 requests that Mr. Adhikary be added as an "Authorized User" and states that he is qualified under "35.690." Both assertions are incorrect.

Mr. Adhikary is being considered as an "Authorized Medical Physicist," as only physicians are "Authorized Users," and the correct regulation for this is 10 CFR 35.51, not 10 CFR 35.690.

Please clarify which NRC license and institution Dr. Burmeister trained Mr. Adhikary at and please clarify whether Mr. Adhikary was obtaining his training and experience in a full time capacity, as it appears that he may have been attending graduate school at the same time.

It also appears that Mr. Adhikary may have obtained the required one year of full time medical physics training and one year of full time work experience at least partially concurrently, according to the dates given on his forms, and we do not know when he received his M.S. degree just yet, which may also have been a factor.

The markings on the enclosed forms also highlight questions we have concerning Mr. Adhikary's qualifications so please ensure that everything is addressed in your written response.

Please submit the requested information no later than September 9, 2011, and address it to my attention by referencing it as "additional information to control number 575383," in order to facilitate proper handling in our offices. If you will be unable to respond by this date, I will void the request temporarily until we receive your written response.

J. Wierzbicki

"Void" means that we take it out of our active database and this administrative procedure "buys" some additional time to prepare a quality response. In addition, please note that this action is taken without prejudice to resubmission.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"... a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

If you have any further questions concerning this matter please contact me at (630) 829-9841. My fax number is (630) 515-1078.

In accordance with 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in black ink that reads "Colleen Carol Casey". The signature is written in a cursive style with a large initial 'C'.

Colleen Carol Casey
Materials Licensing Branch

License No. 21-03646-03
Docket No. 030-02031



RADIATION ONCOLOGY
Young H. Kim, MD, Medical Director
Michael C. Cappelli, MD FACRO
Tushar R. Shah, MD
Khurshid Ahmad, MD FACRO, FACR

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
2443 Warrenville Road Ste 210
Lisle, Illinois 60532-4352

RE: Amendment to U.S. NRC 21-03646-03 License

Dear Sirs,

Please amend our U.S. NRC 21-03646-03 license as follows:

Add:

Bijoyananda Adhikary, M.S.
To be an authorized user for:
Iridium-192 in a remote afterloading brachytherapy unit,
And for calibrations, spot checks and training.

NO "AUTHORIZED MEDICAL PHYSICIST" IS WHAT YOU SHOULD BE ASKING FOR. (AN A.U. IS A PHYSICIAN)
10CFR NO-35.51 IS CORRECT

Therefore, based on Rules and Regulations 35.690 he qualifies for the requested amendment.
(I am sending you form 313A that is needed for our application).

Please contact the Radiation Safety Officer, Jacek G. Wierzbicki Ph.D., telephone: 989-907-8285 if you have any questions or require additional information.

Jacek G. Wierzbicki, Ph.D.

Friday, June 10th, 2011

RECEIVED JUN 16 2011

Accreditations with American College of Radiation Oncology (ACRO) & American College of Surgeons
Affiliated with U of M Cancer Network & Michigan Cancer Research Consortium

800 S. Washington Ave. Saginaw, MI 48601-2594 Phone: (989) 907-8115 Fax: (989) 907-8313 Toll Free: 1-877-738-6672
www.stmarysofmichigan.org

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized Medical Physicist

BIJOYANANDA ADHIKARY

- Requested Authorization(s) (check all that apply)
- 35.400 Ophthalmic use of strontium-90
 - 35.600 Teletherapy unit(s)
 - 35.600 Remote afterloader unit(s)
 - 35.600 Gamma stereotactic radiosurgery 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. Go to the table in 3.c. 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 Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above**
 - a. Go to the table in section 3.c. to document training for new device.
 - b. Skip to and complete Part II Preceptor Attestation
- 3. Education, Training, and Experience for Proposed Authorized Medical Physicist**
 - a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree (DATE CONFERRED?)	Major Field
MASTER OF SCIENCE, RADIOLOGICAL PHYSICS	RADIOLOGICAL PHYSICS
College or University	
WAYNE STATE UNIVERSITY	

→ WAS IT FULLTIME TRAINING + WORK EXPERIENCE IF HE WAS IN GRAD SCHOOL TOO?
 b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services. HE IS NOT LISTED AS AN AMP ON ST. MARY'S LICENSE.

- Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of Dr. JAY BURMEISTER who meets the requirements for an Authorized Medical Physicist.

PLEASE PROVIDE. NO LICENSE NO. WAS GIVEN FOR THIS PERSON AND TRAINING SITE.
- Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of Dr. JACEK WIERZBICKI who meets the requirements for an Authorized Medical Physicist.

WE NEED TO SEE COPY OF ACTUAL DIPLOMA

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics	WAYNE STATE UNIVERSITY (WSU), KARMANOS CANCER INSTITUTE (SEP, 2007 to DEC, 2009) SAINT MARY'S OF MICHIGAN (JULY, 2009 to PRESENT)	SEP, 2007 to PRESENT	07/20/2009 to 06/10/2011
Performing sealed source leak tests and inventories	WAYNE STATE UNIVERSITY (WSU) SAINT MARY'S OF MICHIGAN (SAGINAW, MI)	SEP, 2007 to PRESENT	07/20/2009 to 06/10/2011
Performing decay corrections	WAYNE STATE UNIVERSITY (WSU) SAINT MARY'S OF MICHIGAN	SEP, 2007 to PRESENT	07/20/2009 to 06/10/2011
Performing full calibration and periodic spot checks of external beam treatment unit(s)	WAYNE STATE UNIVERSITY (WSU) SAINT MARY'S OF MICHIGAN (SAGINAW, MI) SETON CANCER INSTITUTE (MARLETTE, MI)	SEP, 2007 to PRESENT	07/20/2009 to 06/10/2011
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)	SAINT MARY'S OF MICHIGAN (SAGINAW, MI)	JULY, 2009 to PRESENT	07/20/2009 to 06/10/2011
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)	SAINT MARY'S OF MICHIGAN (SAGINAW, MI)	JULY, 2009 to PRESENT	07/20/2009 to 06/10/2011

Supervising Individual**

JACEK WIERZBICKI, Ph.D.

License/Permit Number listing supervising individual as an authorized Medical Physicist

U.S. NRC 21-03646-03

for the following types of use:

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent. **PLEASE NOTE**

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

IT APPEARS THAT THIS TRAINING OCCURRED CONCURRENTLY - WAS M.S. DEGREE CONFERRED PRIOR TO THIS TRAINING AND EXPERIENCE - IT IS UNCLEAR.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

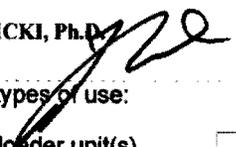
c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Hands-on device operation	07/20/2009 to 06/10/2011		
Safety procedures for the device use	07/20/2009 to 06/10/2011		
Clinical use of the device	07/20/2009 to 06/10/2011		
Treatment planning system operation	07/20/2009 to 06/10/2011		

Supervising Individual

If training is provided by Supervising Medical Physicist, (if more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)

License/Permit Number listing supervising individual as an authorized Medical Physicist

JACEK WIERZBICKI, Ph.D. 

U.S. NRC 21-03646-03

for the following types of use:

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

If Applicable:

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

AUTHORIZED MEDICAL PHYSICIST 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:

1. Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Medical Physicist
10 CFR 35.51(a)(1) and (a)(2).

OR

2. Education, Training, and Experience

I attest that BIJOYANANDA ADHIKARY has satisfactorily completed the 1-year of full-time
Name of Proposed Authorized Medical Physicist
training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

AND

Second Section

Complete the following:

I attest that BIJOYANANDA ADHIKARY has training for the types of use for which authorization
Name of Proposed Authorized Medical Physicist
is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

AND

Third Section

Complete the following:

I attest that BIJOYANANDA ADHIKARY has achieved a level of competency sufficient to
Name of Proposed Authorized Medical Physicist
function independently as an Authorized Medical Physicist for the following:

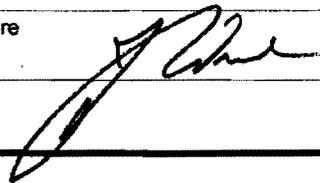
- 35.400 Ophthalmic use of strontium-90
- 35.600 Teletherapy unit(s)
- 35.600 Remote afterloader unit(s)
- 35.600 Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

Complete the following for preceptor attestation and signature:

- I meet the requirements in 10 CFR 35.51, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:
- 35.400 Ophthalmic use of strontium-90
- 35.600 Teletherapy unit(s)
- 35.600 Remote afterloader unit(s)
- 35.600 Gamma stereotactic radiosurgery unit(s)

Name of Preceptor	Signature	Telephone Number	Date
JACEK WIERZBICKI, Ph.D.		(989) 907-8285	06/10/2011

License/Permit Number/Facility Name

**WAYNE STATE
UNIVERSITY**
SCHOOL OF MEDICINE

DEPARTMENT OF RADIATION ONCOLOGY
GERSHENSON RADIATION ONCOLOGY CENTER
4100 JOHN R, DETROIT, MICHIGAN 48201
PHONE: (313) 745-9175
FAX: (313) 745-2314

*THIS LETTER IS INSUFFICIENT -
PLEASE PROVIDE COPY OF THE DIPLOMA
AND OTHER INFORMATION + CLARIFICATIONS
REQUESTED,*

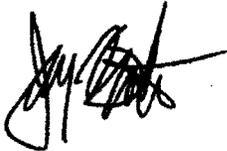
June 7, 2011

(C-Casey)

To Whom It May Concern:

This letter is to certify that Mr. Bijoyananda Adhikary has completed all requirements for the degree of Master of Science in Radiological Physics from the CAMPEP-accredited graduate program within the Wayne State University School of Medicine. Please contact me if you require any further information.

Yours Sincerely,



Jay Burmeister, Ph.D., DABR
Director of Education, Dept. of Radiation Oncology
Wayne State University School of Medicine
Karmanos Cancer Center / Gershenson ROC
4100 John R
Detroit, MI 48201
Tel: (313)745-2483
FAX:(313)745-2314



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 9/2/11 (wty) NUMBER OF PAGES: 9
(including this page)

SEND TO: JACEK WIERZBICKI, Ph.D.

LOCATION: ST. MARY'S OF MICHIGAN

FAX NUMBER: 989-907-8313 **VERIFY BY CALLING SENDER**

FROM: Colleen Carol Casey
(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE *I will be available on Friday Sept. 2, 2011 + out of the office from Sept. 5-9, returning on Sept. 12. Call if you have questions, please. Thank you.*
Colleen Carol Casey

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