



Comprehensive Care for Cancer and Blood Disorders

Hematology/Oncology

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V.L. Randolph, M.D.
J.M. Rothman, M.D.
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M.A. Varghai, M.D.

Radiation Oncology

R.M. Fine, M.D.
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2500 West Twelfth Street
Erie, Pennsylvania 16505
(814) 838-9000
(800) 477-6647
www.trcc.org

NMSS

RE: Change of Personnel
License Number 37-30885-01

03036511

2007 NOV 30 PM 12: 21

RECEIVED
REGION 1

November 27, 2007

U. S. Nuclear Regulatory Commission
Licensing Assistance Section – Nuclear Materials Safety Branch
Region I, 475 Allendale Road
King of Prussia, Pennsylvania 17406-1415

To Whom It May Concern,

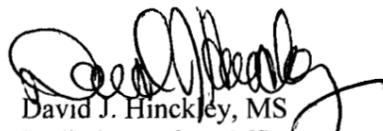
I am writing to attest to the training and full time employment of Ms. Mihaela Mihalache-Leca, MS at The Regional Cancer Center of Erie, Pennsylvania and request her be added to our license as an Authorized Medical Physicist for remote afterloader units.

Ms. Mihalache-Leca's training began at The University of Kentucky where she earned a Master of Science degree in Radiological Medical Physics, September 2005. She became an employee of the Cancer Center in September 2005 and continues working as a full time Medical Physicist. During her employment with The Regional Cancer Center she performed the following tasks as they relate to HDR Remoter Afterloaders:

- a. Decay of Iridium 192 source
- b. Hand Calculation checks of PLATO treatment planning software plans.
- c. Check of source activity, based on decay, listed in PLATO treatment planning software and the Treatment Console software.
- d. Proper use of the HDR Remote Afterloader and treatment planning software, including emergency procedures.
- e. Area radiation surveys include shielding evaluation of the unit and treatment room.
- f. Calibration of the Iridium 192 source and periodic spot checks of the unit.

I served as her preceptor during this time (please see enclosed application).

Regards,


David J. Hinckley, MS
Radiation Safety Officer



Thomas Fucci, Acting CEO
(noted & acknowledged)

141371

NMSS/RGN1 MATERIALS-002



Accredited by
Accreditation Association
for Ambulatory Health Care, Inc.

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

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

Name of Proposed Authorized Medical Physicist
Mihaela Mihalache-Leca, MS

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	Major Field
Masters of Science	Radiological Medical Physics
College or University	
University of Kentucky	

- 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.

Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of David J. Hinckley, MS, DABR who meets the requirements for an Authorized Medical Physicist.

AND

Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of David J. Hinckley, MS, DABR who meets the requirements for an Authorized Medical Physicist.

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	The Regional Cancer Center 2500 West 12th Street Erie, PA 16505 License # 37-30885-01 Nucletron Microselectron HDR Unit	9/19/05 - 9/18/06	9/19/06 - 11/27/07
Performing sealed source leak tests and inventories	The Regional Cancer Center 2500 West 12th Street Erie, PA 16505 License # 37-30885-01 Nucletron Microselectron HDR Unit	9/19/05 - 9/18/06	9/19/06 - 11/27/07
Performing decay corrections	The Regional Cancer Center 2500 West 12th Street Erie, PA 16505 License # 37-30885-01 Nucletron Microselectron HDR Unit	9/19/05 - 9/18/06	9/19/06 - 11/27/07
Performing full calibration and periodic spot checks of external beam treatment unit(s)	The Regional Cancer Center 2500 West 12th Street Erie, PA 16505 License # 37-30885-01 Nucletron Microselectron HDR Unit	9/19/05 - 9/18/06	9/19/06 - 11/27/07
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)	The Regional Cancer Center 2500 West 12th Street Erie, PA 16505 License # 37-30885-01 Nucletron Microselectron HDR Unit	9/19/05 - 9/18/06	9/19/06 - 11/27/07
Performing full calibration and periodic spot checks of remote afterloading unit(s)	The Regional Cancer Center 2500 West 12th Street Erie, PA 16505 License # 37-30885-01 Nucletron Microselectron HDR Unit	9/19/05 - 9/18/06	9/19/06 - 11/27/07
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)	The Regional Cancer Center 2500 West 12th Street Erie, PA 16505 License # 37-30885-01 Nucletron Microselectron HDR Unit	9/19/05 - 9/18/06	9/19/06 - 11/27/07

Supervising Individual**
David J. Hinckley, MS, DABR

License/Permit Number listing supervising individual as an authorized Medical Physicist
37-30885-01

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.

** 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.

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	Has conducted under supervision 15 HDR procedures during the period 8/3/07 - 11/27/07. Also included: QA required testing, daily and source exchange.		
Safety procedures for the device use	9/19/06 - 11/27/07 have reviewed emergency/safety procedures including error codes and response on numerous occasions (in conjunction with actual tx.)		
Clinical use of the device	Has participated/ conducted under my supervision 15 HDR procedures during the period 8/3/07 - 11/27/07. This included all aspects of device operation.		
Treatment planning system operation	Has planned under my supervision 10 HDR procedures during the period 9/19/06 - 11/27/07. Formal Nucletron tx planning training occurred 10/11/07.		
Supervising Individual <small>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.)</small>		License/Permit Number listing supervising individual as an authorized Medical Physicist	
David J. Hinckley, MS, DABR		37-30885-01	
for the following types of use:			
<input checked="" type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> 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 Mihaela Mihalache-Leca, MS 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 Mihaela Mihalache-Leca, MS 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 Mihaela Mihalache-Leca, MS 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)

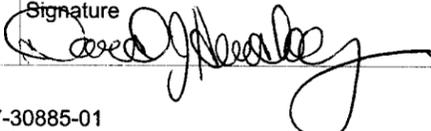
AND

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
David J. Hinckley, MS, DABR		814-838-0450	11/27/07
License/Permit Number/Facility Name			
The Regional Cancer Center License #37-30885-01			

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

11/27/2007, and to inform you that the initial processing which includes an administrative review has been performed.

ATCMB. 37-30885-01
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** 141371.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader