

February 16, 2011

Br 4

RECEIVED
REGION 1
2011 FEB 17 AM 11:25

U. S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, PA 19406

RE: Amendment request
License No. 07-17618-01
Docket No. 030-13060
Nanticoke Memorial Hospital

To Whom It May Concern:

Please amend the above referenced license to remove Vladimir Ioffe, M.D. Dr. Ioffe is no longer associated with the facility. Please also add Dr. Vincenzo De Masi, M.D. as authorized user of radioactive material listed under 10 CFR 35.400. Board certification and preceptor attestation forms have been obtained and completed.

If there are any questions or if additional information is needed regarding the above matter, please contact Marianna Retzlaff, CNMT at 302-629-6611, ext. 2385 or Mr. Malek Daneshvar (consultant, Krueger-Gilbert Health Physics, Inc.) at 410-665-5447.

Sincerely,

Messy Babinski
Hospital Administrator

phone (302) 629-6611
fax (302) 629-2493
801 Middleford Road
Seaford, Delaware 19973
nanticoke.org

574458

**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

Dr. Vincenzo DeMasi

State or Territory Where Licensed

Delaware

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

- a. Provide a copy of the board certification.
- b. 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.
- c. Skip to and complete Part II Preceptor Attestation.

2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above

- a. Go to the table in section 3.e. to document training for new device.
- b. Skip to and complete Part II Preceptor Attestation.

3. Training and Experience for Proposed Authorized User

- a. 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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

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:	
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking survey meters for proper operation		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material		<input 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 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		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

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:	
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

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: <input 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		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

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			
Safety procedures for the device use			
Clinical use of the device			
Supervising Individual. <i>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.)</i>		License/Permit Number listing supervising individual as an Authorized User	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> 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 Dr. Vincenzo DeMasi 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 _____ 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 _____ 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 _____ has received training required in 35.690(c) for device
Name of Proposed Authorized User
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

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

AND

Fourth Section

I attest that _____ has achieved a level of competency sufficient to
Name of Proposed Authorized User
achieve a level of competency sufficient to function independently as an authorized user for:

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	Signature	Telephone Number	Date
MANOJ JAIN M.D.	<i>Manoj Jain M.D.</i>	302-629-6611	2/18/2011
License/Permit Number/Facility Name			
07-17618-01		Natick Memorial Hospital	

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology,
and the Association of University Radiologists

Hereby certifies that

Vincenzo De Masi, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of

The American Board of Radiology

On this twenty-sixth day of May, 1988

Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Radiation Oncology

M. Paul Capp. M.D.

President

Frank H. Zuckerman, M.D.

President



STATE OF DELAWARE

NOT TRANSFERABLE

C1-0004062

DIVISION OF PROFESSIONAL REGULATION

801 STATE HOUSE
CORNER BOWLING GREEN 203
DOVER DE 19901-5007

EXPIRATION DATE 03/31/2011

Physician M.D.

Vincenzo DeMasi

MAILING ADDRESS

Vincenzo DeMasi

PROFESSIONAL LICENSE

THE PERSON NAMED IS HEREBY LICENSED TO
PRACTICE IN THE PROFESSION INDICATED ABOVE THIS
LICENSE ISSUED UNDER THE LAWS OF THE STATE OF DELAWARE

LICENSEE SIGNATURE

192391

Please review the information on your license and notify us of any changes needed.

Division of Professional Regulation is proud of our professional and responsive customer service. Visit our web site at dpr.delaware.gov for essential reference information and access to online license services 24 hours a day, 7 days a week.

To sign up for online license services, you will need a Registration Code.
Your Registration Code is: 72132402
(Please retain for future use with online services.)



Need to change your mailing address, email address or phone number? Update your contact information online so that renewal notices and other critical mailings will reach you. (Note: This service is not available for some kinds of licenses, such as real estate licenses.)

Need to renew? Submit your renewal application and pay your renewal fee by credit card online. We'll send you a notice when renewal is available on our secure web site.

Need to check the status of a license? Online license verification, including license status and disciplinary information, is available to the general public on our web site.

Need questions about your profession? Please check our web site first for license law, Rules and Regulations, and frequently asked questions (FAQ's).

Need a form? Forms such as verification requests are a click away.

Want to attend a meeting of the board or commission for your profession? Click on the "Meeting Calendar" on your profession's web page.

Can't find what you need online? Just send an email to customerservice.dpr@state.de.us and let us know what you need.

When required to display your professional license, you may display either the license certificate above or the wallet card below.

STATE OF DELAWARE
DIVISION OF PROFESSIONAL REGULATION
PROFESSIONAL LICENSE
Physician M.D.
C1-0004062
03/31/2011

Vincenzo DeMasi

THIS IS YOUR LICENSE CARD.

NANTICOKE MEMORIAL HOSPITAL
 Initial Delineation Form
DEPARTMENT OF RADIOLOGY
RADIATION ONCOLOGY

Name: VINCENZO DE MASI 12/10/09 to 08/01/2011

Radiation Oncology is the branch of Radlology which deals with the therapœutic applications of high energy radiation in the management of disease, especially malignant tumors.

Applicants for clinical privileges In Radlatlon Oncology must:

1. Be certified by the American Board of Radiology (or in the certification process)

Advancement Requirements: Ten (10) case reviews will be required for consideration of advancement from provisional staff to full privileges with at least one (1) case for initial consult while an inpatient.

CATEGORY I - II Physicians with these privileges must have satisfactorily completed a training program in Radiation Oncology

Hospital	GROUP	PRIVILEGE	Privilege Requested	Privilege Approved
X		Provide consultations for patients and direct course of treatment for conditions for which the patients are admitted.	✓	✓
X		Comprehensive evaluation of patients with cancer and related disorders	✓	✓
X		Prescribe/supervise radiation therapy procedures	✓	✓
X		Summarize/authenticate reports	✓	✓
X		Endoscopies (indirect laryngoscopy, nasopharyngoscopy, fiber optic laryngoscopy)	✓	✓

Hospital	GROUP	PRIVILEGE	Privilege Requested	Privilege Approved
X		Computer tumor simulation and treatment planning	✓	✓
X		Use of linear accelerator for external beam patient treatment	✓	✓
X		Perform intraluminal, endocavilary and interstitial implants	✓	✓
X		Low Dose Rate (LDR) Brachytherapy	✓	✓

[Signature]
11/16/09

NANTICOKE MEMORIAL HOSPITAL
Initial Delineation Form
DEPARTMENT OF RADIOLOGY
RADIATION ONCOLOGY

Name: VINCENTZO DE MARI 12/10/09 to 08/01/2011

CATEGORY III includes Category I and II: Physicians with these privileges are expected to have training, experience and competence on a level commensurate with that provided by specialty training, although not necessarily at the level of a subspecialist. Board certification is key benchmark.

Note: These procedures require proof of additional training and competence beyond residency training, as well as separate requirements for proctoring and/or observation (minimum three cases each).

Hospital	Radio	PRIVILEGE	Privilege Requested	Privilege Approved
X		Prostate Seed Implant	✓	✓

[Signature]
Signature

7/22/09
Date

[Signature]
Department Chief of Radiology

11/16/09
Date

[Signature]
LCRP Chairperson

Date

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

2/16/2011, and to inform you that the initial processing which includes an administrative review has been performed.

Amend. 07-17618-01
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** 574458.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.