

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 2011 JAN 18 AM 11: 19

Gentlemen:

Please amend the above referenced license to remove Louis F. Owens, M.D. as an authorized user and Radiation Safety Officer once Dr. Vennos, the proposed Radiation Safety Officer has been approved. Dr. Vennos is currently Radiation Safety Officer on Maryland Radioactive Material License Number MD-45-021-01 and meets the qualifications of a Radiation Safety Officer as outlined in 10CFR 35.50. Dr. Vennos has received training for 35.400 by the current Authorized User, Dr. Jain. Please also add the following Doctors as authorized users of radioactive material listed under 10 CFR 35.100 and 10 CFR 35.200:

Robert Corcoran, M.D.
Phillip Hugo, M.D.
Gerard J. F. Hogan, M.D.
Thomas Riccio, M.D.
Mario Todorov, M.D.

Alexander Zito, M.D.
David Chung, M.D.
Assen Todorov, M.D.
William Reid, M.D.
Marvin E. Nielsen, M.D.

Peter Libby, M.D. Simmi Chawla, M.D. Andrew Vennos, M.D. Michael Marks, M.D.

Please also add Dr. DeMasi as authorized users of radioactive material listed under 10 CFR 35.400.

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

Sincerely,

Hospital Administrator

phone (302) 629-6611 fax (302) 629-2493 801 Middleford Road

Seaford, Delaware 19973

nanticoke.org

574264

NMSS/RGN1 MATERIALS-002

^{*}Radioactive Materials License attached for State of Maryland

IRC FORM 313A (RSO)	U.S. NUCLEAR REGULATORY COMMISSION		
RADIATION SAFETY OFFI AND PRECEI	CER TRAINING AND EXPERIENCE PTOR ATTESTATION CFR 35.50]	APPROVED I EXPIRES: 10	3Y OMB: NO. 3150-012 //31/2008
Name of Proposed Radiation Safety Officer			
Andrew Venn	os, MD		
	e authorizes the following medical uses (check all		
35.100 35.200 3	$\boxed{35.400} \boxed{35.500} \boxed{3}$	5.600 (remot	e afterloader)
35.600 (teletherapy)		5.1000 ()
	PART I TRAINING AND EXPERIENCE (Select one of the four methods below)		
application or the individual must have	ard certification, must have been obtained within to obtained related continuing education and experied to dates, duration, and description of continuing e	ence since the	required training
1. Board Certification			
a. Provide a copy of the board ce	rtification.		
 b. Use Table 3.c. to describe train all types of medical use on the 	ing in radiation safety, regulatory issues, and ema license.	ergency proce	edures for
c. Skip to and complete Part II Pro	eceptor Attestation		
a. Use the table in section 3.c. to	o describe training in radiation safety, regulatory is types of medical use for which recognition as RS	ssues, and er	
3. Structured Educational Progra	OR Im <u>for Proposed Radiation Safety Officer</u>		
a. Classroom and Laboratory Tra		•	
Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	:	7,04.0	Training
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			,
Radiation dosimetry			
	Total Hours of Training:		
P.C. FORM 313A (RSO) (2-2007)	PRINTED ON RECYCLED PAPER		FAGE I

NRC FORM 313A (RSO) (2-2007) U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

 Supervised Radiation Safety Experience (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
		· v
	and the second s	
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Jsing administrative controls to avoid nistakes in administration of byproduct naterial		A
nateria.		
		x
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	•	,
association prossuatos		
Jsing emergency procedures to control by product material		
		, r · ·
, .		
Disposing of byproduct material		
		•
icensed Material Used (e.g., 35.100,		
15.200, etc.)+		
		•
		•

Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.300, 35.500, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

Structured Educational Program for Propo	sed Radiation Safety Officer (continued)	
Supervised Radiation Safety Experience	(continued)	
(If more than one supervising individual is copies of this section.)	necessary to document supervised work experience, p	provide multipl
Supervising Individual	License/Permit Number listing supervising indi-	vidual as a
	Radiation Safety Officer	
This license authorizes the following medical	uses:	******* *******************************
35.100 35.200 35.300	35.400	
35.500 35.600 (remote afterload	er) 35.600 (teletherapy)	
35.600 (gamma stereotactic radiosurgery) 35.1000 ()	
Describe training in radiation safety, regularise on the license.	atory issues, and emergency procedures for all types o	
Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and	University of Maryland	
emergency procedures for 35.100, 35.200, and 35.500 uses	Residency in Diagnostic Radiology	1992-199
Radiation safety, regulatory Issues, and		de Servicio de la constanta d
emergency procedures for 35.300 uses		
	·	· ··.
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Nanticoke Momorial Hospital Cancer Care Center	10/20/10
	Dr. Jain - AU for Nanticoke (Natura)	12/30/ 40
Radiation safety, regulatory issues, and	21. 22. 101 Journage and links	mi
emergency procedures for 35.600 - eletherapy uses		
Radiation safety, regulatory issues, and		
mergency procedures for 35.600 - remote afterloader uses		3
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma		
tereotactic radiosurgery uses		٠.
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify		
ise(s):		

NRC FORM 313A (RSO)	U.S. NUCLEAR REGULATORY COMMISSION
RADIATION SAFETY OFFICER TRAINING AND EXPERI	ENCE AND PRECEPTOR ATTESTATION (continued)
3. Structured Educational Program for Proposed Radiat	ion Safety Officer (continued)
 Training in radiation safety, regulatory issues, and emelicense (continued) 	ergency procedures for all types of medical use on the
Supervising Individual If training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)	License/Permit Number listing supervising individual
Dr. Jain	
License/Permit lists supervising individual as:	
Radiation Safety Officer Authorized User	Authorized Nuclear Pharmacist
Authorized Medical Physicist	
Authorized as RSO, AU, ANP, or AMP for the following	g medical uses:
35.100 35.200 35.300	⊠ 35.400
35.500 35.600 (remote afterloader)	35.600 (teletherapy)
35.600 (gamma stereotactic radiosurgery)	35.1000 ()
d. Skip to and complete Part II Preceptor Attestation.	
OR	
4. Authorized User, Authorized Medical Physicist, or	Authorized Nuclear Pharmacist Identified on
the licensee's license	
a. Provide license number.	
 b. Use the table in section 3.c. to describe training in a procedures for all types of medical use on the licen 	
c. Skip to and complete Part II Preceptor Attestation.	
PART II PRECEPTO	DR ATTESTATION
Note: This part must be completed by the individual's precep	tor. The preceptor does not have to be the supervising verifies training and experience required. If more than
Check one of the following:	
1. Board Certification	
I attest that Dr. Vennes ha	s satisfactorily completed the requirements in
10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) a	nd (a)(2)(ii); or 35.50(c)(1).
OR	
2. Structured Educational Program for Proposed Radia	ition Safety Officers
l attest that · ha	s satisfactorily completed a structural educational
Name of Proposed Radiation Safety Officer program consisting of both 200 hours of classroom and radiation safety experience as required by 10 CFR 35.5	i laboratory training and one year of full-time
OR	
OR	PAGE 4

C1-0007043

No. 2581---P. 5/5 NOT TRANSFERABLE

DIVISION OF PROFESSIONAL REGULATION SET Silver Lake Bivd.

Cannon Building, Suite 203 Dover DE 19904-2467

PROFESSION:

Physician M.D.

EXPIRATION DATE.

03/31/2011

ISEUED TO

Manoj Jain

MAILING ADDRESS

Manoj Jain

PROFESSIONAL LICENSE

IS CERTIFIES THAT THE PERSON NAMED IS HEREBY LICENSED TO HOUGH OR ENGAGE IN THE PROFESSION INDICATED ABOVE. THIS COMENT IS CULY ISSUED UNDER THE LAWS OF THE STATE OF DELAWARE.

LICENSEE SIGNATURE

183119

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

The Division of Professional Regulation is proud of our professional and responsive customer service. Visit our web site at www.dpr.dclaware.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: 22418417

(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 facilities.)
- Time to renew? Submit your renewal application and pay your renewal fee by credit card online. We'll send you a notice when the 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.
- 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.

If you are 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

DPESSION: ENSE NO.

Physician M.D. C1-0007063

PIRATION DATE.

UED TO:

03/31/2011 Manōj Jaln

THIS IS YOUR LICENSE CARD. **CUT THIS PORTION TO** FIT IN YOUR WALLET.

CENSEE SIGNATURE

HOTTRUCEFERAGES

504244-02 1/03

NRC FORM 313A (RS	90)	U.S. NUCLEAR REGULATORY COMMISSION
RADIATION SA	FETY OFFICER TRAINING AND EXPERIENCE A	AND PRECEPTOR ATTESTATION (continued)
Preceptor <u>Attestat</u>	ion (continued)	
First Section (con Check one of the f		
3. Additiona	Authorization as Radiation Safety Officer	
X I attest that	t <u>Dr. Vennos</u> is an Name of Proposed Radiation Safety Officer	
Autt	horized User Authorized	ed Nuclear Pharmacist
Auth	horized Medical Physicist	
aspects	ed on the Licensees license and has experience wi s of similar type of use of byproduct material for wh on Safety Officer responsibilities	
	AND	
Second Section Complete for all (d	check all that apply):	
I attest that	Dr. Vennos has training i	in the radiation safety, regulatory issues, and
emergency pro	ocedures for the following types of use:	·
∑ 35.100		
35.200		
35.300	oral administration of less than or equal to 33 mil which a written directive is required	illicuries of sodium iodide I-131, for
35.300	oral administration of greater than 33 millicuries	of sodium iodide I-131
35.300	parenteral administration of any beta-emitter, or a a photon energy less than 150 keV for which a w	a photon-emitting radionuclide with written directive is required
35.300	parenteral administration of any other radionuclid required	de for which a written directive is
∑ 35.400		·
☑ 35.500		
35.600	remote afterloader units	
35.600	teletherapy units	
35.600	gamma stereotactic radiosurgery units	
35.1000	emerging technologies, including:	
•		

	AN	ID		
hird Section complete for ALL				
lattest that Dr. Vennos Name of Proposed Radia		achieved a level of r	adiation safety knowle	edge
sufficient to function independently	as a Radiation Safety	y Officer for a medic	al use licensee.	
ourth Section complete the following for Preceptor	Attestation and sign	naturo		:
am the Radiation Safety Officer for	Nantioke	Memorial Name of Fed	Hospital	
icense/Permit Number: 67 -	17618-01			
•				•
·				<i>:</i>
•		•	· .	
	•			
			•	,
				·
me of Preceptor	Signature 2		Telephone Number	Date
Louis F. Ovenst. mg	Law Kill	wy we	302-429-6411	1/11/11

EM MANTERM BURNED OF THE COMPANIES OF TH

American College of Pladiology, the American Docutgen Day Society, the American College of Pladiology, the American Docutgen Day Society, the American Docuty of North America, the Section on Dadiology of the American Aledical Association, the American Society for Therapeutic Dadiology and Oncology, the Association of University Dadiologists, and American American Association of University Dadiologists, and American American Association of University Dadiologists, and American Association of University Dadiologists, and American American Association of University Dadiologists, and American American Association of University Dadiologists, and American American Dadiologists, and Dadiolog

Andrew Dianysias Vennas, MD

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 fourth day of November, 1996 Thereby demonstrating to the satisfaction of the Board Stas jursued an accepted course of graduate study that he is qualified to practice the specialty of

Piagnostic Radiology



Secretary Tro De Vand Capp. M. 7.





MARYLAND DEPARTMENT OF THE ENVIRONMENT

1800 Washington Boulevard • Baltimore MD 21230 410-537-3000 • 1-800-633-6101

Jortin ()* Malley Governor

Anthony G. Brown Lieutenant Governor Shari T. Wilson Secretary

Robert M. Summers, Ph.D. Deputy Secretary

April 19, 2010

Andrew D. Vennos, M.D., Radiation Safety Officer Peninsula Imaging, LLC 1655 Woodbrooke Drive Salisbury, MD 21804

RE: Radioactive Material License # MD-45-021-01

Dear Dr. Vennos:

Enclosed is your renewed radioactive materials license, which is being issued in accordance with Maryland Radiation Law and Code of Maryland Regulations (COMAR) 26.12.01.01, Regulations for the Control of Ionizing Radiation. This renewal has been prepared based on your application received in this office on September 18, 2009, and all relevant supplemental information received as of March 30, 2010. Please review it carefully to ensure it is complete and accurate.

Licensees are inspected at least once during the 7-year life of the license. Inspections are performed with greater frequency for more complex licenses. If you have any questions or need assistance on any aspect of this license renewal or any other matter regarding radioactive materials, please contact Mr. Raymond E. Manley, of the Radioactive Materials Division at 410-537-3301. You may also reach our office toll-free by dialing 1-800-633-6101 and requesting extension 3301 or via facsimile at 410-537-3198. Finally the MDE web page, which contains information about all MDE areas of interest, can be accessed at http://www.mde.state.md.us/arma/Programs/Radiolog/radiolog.html.

Roland G. Fletcher, Manager IV Radiological Health Program

Air and Radiation Management Administration

Enclosures:

License amendment renewal (10)

Code (02201)



RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

Page 1 of 4

Pursuant to the Maryland Radiation Act, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. The license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below.

. Name: Peninsula Imaging, LI ₂ C 2. Address: 1655 Woodbrooke Drive,		3. License No.: 4. Amendment N	MD-45-021-01 No.: 10 RENEWAL; Code 02201
Salisbury, Maryland 21804	4	5. Expiration Da	·
5. Radioactive material (element and nass number)	7. Chemical and/or p	ohysical form	8. Maximum amount of activity which licensee may possess at any one time
A. Any radioactive material listed in COMAR 26.12.01.01 § G.100	A. Any form listed 26.12.01.01 § G.		As needed to perform diagnostic studies
3. Any radioactive material listed in COMAR 26.12.01.01 § G.200	3. Any form listed 26.12.01.01 § G.		B. As needed to perform diagnostic studies
C. Fluorine-18	C. Fluorodeoxygluo	cose	C. As needed to perform diagnostic studies
D. Cobalt-57	D. Sealed Source		D. No source to exceed 15 millicuries
E. Cesium-137		PL CS-20 EG-0111	E. 20 millicuries each; no more than 2 sources on site
F. Technetium-99m	. Pertechnetate		F. As needed
G. Sodium-22	G. Sealed Source: U G	PL NA-0.15 F-0227	G. 0.15millicuries each; no more than 2 sources on site
I. Germanium-68	l. Scaled Source		II. No source to exceed 1.5 millicuries (55MBq); no more than 2 sources on site
9. Authorized Use(s): A. Any uptake, dilution and excre	ction procedure listed	d in COMAR 26.1	2



RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

Page 2 of 4

License Number: MD-45-021-01

Amendment Number: 10

CONDITIONS

- B. Any imaging and localization procedure listed in COMAR 26.12.01.01 § G.200;
- C. Diagnostic imaging;
- D. Reference and/or calibration source, dose calibrator quality control;
- E. Instrument quality control and calibration;
- F. Transmission source.
- 10. The authorized place of uselis the address in item 2. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address.
- 11A. The radiation protection program shall be under the supervision of Andrew D. Vennos, M.D.

11B. Radioactive material shall be used by or under the supervision of:

Name	Authorized Use	Name	Authorized Use
Robert Corcoran, M.D.	G.100, G.200, 6A-AF	Assen Todorov, M.D.	G.100, G.200, 6A-AF
Alexander Zito, M.D.	G.100, G.200, 6A-AF	Andrew Vennos, M.D.	G.100, G.200, 6A-AF
Peter Libby, M.D.	G.100, G.200. 6A-AF	Thomas Riccio, M.D.	G.100, G.200, 6A-AF
Phillip Hugo, M.D.	G.100, G.200, 6A-AF	William Reid, M.D.	G.100, G.200, 6A-AF
David Chung, M.D.	G.100, G.200, 6A-AF	Michael Marks, M.D.	G.100, G.200, 6A-AF
Simmi Chawla, M.D.	G.100, G.200, 6A-AF	Mario Todorov, M.D.	G.100, G.200, 6A-AF
Gerard J. F. Hogan, M.D.	G.100, G.200, 6A-AF	Marvin E. Nielsen, M.D.	G.100, G.200, 6A-AF

- 12. The licensee shall comply with all appropriate provisions of COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation," and shall possess a copy of these regulations.
- 13A. Each sealed source containing radioactive material, other than Hydrogen-3 with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6)months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.
- 13B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of a device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate



RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MAYERIAL LICENSE

Page 3 of 4

License Number: MD-45-021-01

Amendment Number: 10

CONDITIONS

- 13C. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.
- 13D. If the test reveals the presence of 0.005 microcuric or more of removable contamination, the licensec shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Administrator, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230, describing the equipment involved, the test results, and the corrective action taken.
- 13E. Test for leakage and/or contamination shall be performed by Krueger-Gilbert Health Physics., or by other persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission or another Agreement State to perform such services.
- 13). Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- 13G. Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been tested within six months prior to the date of use or transfer.
- 14. Scaled sources containing radioactivity shall not be opened.
- 15. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for three (3) years from the date of the inventory for inspection by the Department, and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.
- 16. The licensee may use Calicheck or Lincator Device for doing lincarity tests of his dose calibrator provided he follows the procedures in the respective manual.
- 17. Food and beverage containers shall not be discarded in radioactive or normal trash containers in licensee's areas utilizing radioactive materials.
- 18. The licensec shall not transfer ownership and/or control of this license to any person or entity without providing required information regarding the transfer for the agency's review and without receiving written authorization for the transfer by the agency.
- 19A. The licensee shall not make any false statement, representation, or certification in any application, record, report, plan, or other document regarding radiation levels, tests performed or radiation safety conditions or practices. Additionally, the licensee shall not falsify, tamper with, or render inaccurate any monitoring device or method.



RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

Page 4 of 4

License Number: MD-45-021-01

Amendment Number: 10

CONDITIONS

- 19A. The licensee shall not make any false statement, representation, or certification in any application, record, report, plan, or other document regarding radiation levels, tests performed or radiation safety conditions or practices. Additionally, the licensee shall not falsify, tamper with, or render inaccurate any monitoring device or method.
- 19B. Violation of any term, condition, or regulation could subject the licensee to administrative or civil penalty or criminal prosecution, as specified in Title 8, Radiation, of the Article Environment of the Annotated Code of Maryland.
- 20. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements representations, and procedures contained in:
 - > Renewal application dated September 15, 2009, with attachments;
 - > Letter dated September 17, 2009, revising dose calibrator linearity testing procedures;
 - Facsimile dated March 26, 2010;
 - > Facsimile dated March 30, 2010.

COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

March 30, 2010

DKM 709 3/30/10

Roland G. Fletcher, Manager IV Radiological Health Program



MARYLAND DEPARTMENT OF THE ENVIRONMENT

1800 Washington Boulevard • Baltimore MD 21230 410-537-3000 • 1-800-633-6101

...artin O' Malley Governor

Anthony G. Brown Lieutenam Governor MAR 2 9 2010

Shari T. Wilson Secretary

Robert M. Summers, Ph.D. Deputy Secretary

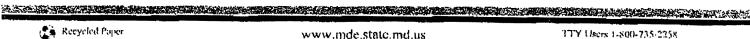
Andrew D. Vennos, M.D., Radiation Safety Officer Peninsula Imaging, LLC 1655 Woodbrooke Drive Salisbury, MD 21804

Re: IRI- 09-01 MARYLAND ENDORSEMENT OF NRC "EXEMPTION FROM 10 CFR PART 32 AND 10 CFR PART 35 REQUIREMENTS ON PROCUREMENT AND TRANSFER OF TECHNETIUM-99M, AND CALIBRATION OF INSTRUMENTATION USING TECHNITIUM-99M"

Dear Dr. Vennos:

The Maryland Department of the Environment's (MDE) Radiological Health Program (RIIP) is issuing this Information and Regulatory Interpretation Notice (IRI) 09-01 to inform diagnostic medical licensees of RHP's endorsement of the July 16, 2009 United States Nuclear Regulatory Commission's exemption titled, "EXEMPTION FROM 10 CFR PART 32 AND 10 CFR PART 35 REQUIREMENTS ON PROCUREMENT AND TRANSFER OF TECHNETIUM-99M, AND CALIBRATION OF INSTRUMENTATION USING TECHNITIUM-99M." In Maryland the exemption will be specific to COMAR 26.12.01.01 Part C and Part G requirements.

The recent shutdown of key nuclear reactors has demonstrated the fragility of molybdenum-99 production and has resulted in a current shortage and potential future shortage of technetium-99m. The reality of aging reactors has prompted the Nuclear Regulatory Commission to publish exemptions to 10 CFR Parts 32 and 35 concerning the transport of Technetium-99m and the performance of dose calibrator linearity. The Radiological Health Program has decided to allow Maryland licensees affected by the technetium-99m shortage to be covered by these exemptions, with the caveat that those licensees fully understand the licensing and documentation requirements needed to implement the exemptions.



www.mde.state.md.us

TTY Users 1-800-735-2258 Via Maryland Relay Service Dr. Vennos Page Two

The NRC exemption document (attached) should be carefully examined for application to your licensed activities. A basic summary of the exemptions as applied in Maryland is listed below:

1. Transportation of Technetium-99m or Technetium-99m

Transportation of technetium-99m and technetium-99m radiopharmaceuticals is allowed between medical licensees, and licensees are exempted from commercial distribution regulations. This exemption applies is in times of shortages only, and the material must be prepared and transported in accordance with radioactive

materials transportation requirements using adequate shielding, appropriate containers, and the proper shipping labels. Proper documentation must be maintained.

2. Dose Calibrator Linearity

Quarterly dose calibrator linearity may be postponed if certain conditions are met:

- a. The licensee must request an amendment to the license requesting the exemption from performing quarterly linearity if a shortage prevents it, but with the provision that as soon as technetium should become available, the linearity will be performed.
- b. The supplier must provide documentation to the licensee that the supplier is unable to provide technetium -99m for linearity.
- c. Time-dependent linearity can be performed with reduced activity in times of shortage.
- d. Time-dependent linearity can be postponed until sufficient activity can be obtained.
- e. Time-dependent linearity must be performed as soon as the supplier is able to provide sufficient activity
- f. Those with lead-sleeved linearity devices should be able to perform linearity measurements and use the technetium-99m used for performing linearity for patient dosing.

Sep. 22 2010 08:53AM P9

FAX NO. : 410 749 1270

Dr. Vennos Page Three

Exemptions to the COMAR 26.12.01.01 Section G.60.B(b)(3) will be examined during inspections. Should you have any questions regarding this information notice, please contact Barbara Park or me at (410) 537-3301. You may also reach our office toll-free by dialing 1-800-633-6101 and requesting extension 3301. Also, you may contact this office via facsimile at (410) 537-3198.

Sincerely,

Raymond E. Manley, Chief Radioactive Material Licensing

Compliance Division

Air and Radiation Management Administration

Radioactive Material Use Codes: 02110, 02120, 02201, 02220, and 02200

Enclosurc(s): NRC Exemption Notice dated July 16, 2009 titled, "EXEMPTION FROM 10 CFR PART 32 AND 10 CFR PART 35 REQUIREMENTS ON PROCUREMENT AND TRANSFER OF TECHNETIUM-99M, AND CALIBRATION OF INSTRUMENTATION USING TECHNITIUM-99M.

NRC FORM 313A (AUS)	U.S. NUCLE	AR REGULATORY COMMISSION		
AUTHORIZED USER AND PRECE (for uses defined	TRAINING AND I EPTOR ATTESTA d under 35.400 an 90, 35.491, and 3	TION d 35.600)	APPROVED BY EXPIRES: 3/31/	OMB: NO. 3150-012 /2012
Name of Proposed Authorized User		State or Territory Where Licens	ed	
Dr. Vincenzo DeMa	si	Delaware		
	anual brachytherapy s		apy unit(s)	
Authorization(s) 35.400 Option (check all that apply)	ohthalmic use of stront	ium-90 🔲 35.600 Gamma :	stereotactic rac	diosurgery unit(s)
(Check all that apply) 35.600 Re	emote afterloader unit(s)		
		AND EXPERIENCE nree methods below)		
* Training and Experience, includin date of application or the individual required training and experience and experience related to the use	al must have obtained was completed. Provi	related continuing education	and experienc	e since the
X 1. Board Certification				
a. Provide a copy of the board ce	ertification.			
 For 35.600, go to the table in 3 which authorization is sought. 	3.e. and describe traini	ing provider and dates of train	ning for each ty	pe of use for
c. Skip to and complete Part II P	receptor Attestation.			
2. Current 35.600 Authorized Use	er Requesting Addition	onal Authorization for 35.60	00 <u>Use(s) Che</u>	cked Above
a. Go to the table in section 3.e.	to document training fo	or new device.		
b. Skip to and complete Part II P	receptor Attestation.			
3. Training and Experience for	Proposed Authorized	l User		
a. Classroom and Laboratory Tra	aining 35.490	35.491 35.6	690	
Description of Training	Locati	on of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation				
Radiation protection				
Mathematics pertaining to the use and measurement of radioactivity				
			and a supplied the acquired decay of pitch long as, from long \$ \$1000 as \$1000 as a supplied to a supplied to a	

NRC FORM 313A (AUS) (3-2009)

Radiation biology

PRINTED ON RECYCLED PAPER

Total Hours of Training:

PAGE 1

Training and Experience for Propos	sed Authorized User (con	tinued)		
 Supervised Work and Clinical Expense necessary to document supervised wo 	rience for 10 CFR 35.490 (ork experience, provide mul	(If more than one tiple copies of th	e supervising indi nis page.)	vidual is
Supervised Work Experience		Total Hours of Experience:		
Description of Experience Must Include:	Location of Experience Permit Number of I		Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			Yes No	
Checking survey meters for proper operation			Yes No	
Preparing, implanting, and safely removing brachytherapy sources			Yes No	
Maintaining running inventories of material on hand			Yes No	
Using administrative controls to prevent a medical event involving the use of byproduct material			Yes No	
Using emergency procedures to control byproduct material			Yes No	
Clinical experience in radiation oncology as part of an approved formal training program	Location of Exp Permit Num	erience/License	or	Dates of Experience*
Approved by: Residency Review Committee for Radiation Oncology of the ACGME				
Royal College of Physicians and Surgeons of Canada Committee on Postdoctoral				
Training of the American Osteopathic Association				
Supervising Individual	License/l Authorize		ting supervising ind	ividual as an

Training and Experience for Propo	sed Authorized User (continued)		
c. Supervised Clinical Experience for			
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 list Authorized User	ing supervising ind	lividual as an
d. Supervised Work and Clinical Expe	erience for 10 CFR 35.690	And the second s	
Remote afterloader unit(s)		na stereotactic ra	diosurgery un
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		Yes No	
Preparing treatment plans and calculating treatment doses and times		Yes No	
Using administrative controls to prevent a medical event involving the use of byproduct material		Yes No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		Yes No	
Checking and using survey meters		Yes No	
Selecting the proper dose and how it is to be administered		Yes	

PAGE 3

Clinical experienc	t and Cillical Exp	erience for 10 (CFR:	35.690 (continued)		
	Clinical experience in radiation		ocation of Experience/License or Permit Number of Facility			Dates of Experience
pproved by:	ina mg/ t inina magalinina a ngagaina a ngagaininangagaipi da magagain inangagipi ana gagaipi <mark>mangag</mark> aipinangag	a framework (1997) - 1994 - 1994 - 1994 - 1994 - 1994 - 1994 - 1994 - 1994 - 1994 - 1994 - 1994 - 1994 - 1994			10 - 10 - 10 - 10 - 10 - 10 - 10 - 10 -	
Residency Rev Committee for I Oncology of the	Radiation					
Royal College of and Surgeons of	of Canada					
Committee on F Training of the Osteopathic As	American					
upervising Individua	I			License/Permit Number list Authorized User	ing supervising ind	dividual as an
For 35.600, des sought.	cribe training prov	ider and dates	of tra	aining for each type of use	e for which autho	orization is
Description of Training			Training Provider and Dates			
	Remote Afte	erloader		Teletherapy		Stereotactic osurgery
evice operation						
afety procedures r the device use						
inical use of the			are the second of the second			
dividual (If more than	ual. If training provide one supervising individ work experience, prov	dual is necessary		nse/Permit Number listing su prized User	upervising individu	al as an
uthorized for the fo	ollowing types of u	use:		nit(a)	stereotactic radio	spurgony unit/o\

•

RC FORM 313A (AUS) U.S. NUCLEAR REGULATORY COMMISSION					
	AUTHORIZED	JSER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
		PART II - PRECEPTOR ATTESTATION			
ir	ndividual as long	e completed by the individual's preceptor. The preceptor does not have to be the supervising as the preceptor provides, directs, or verifies training and experience required. If more than necessary to document experience, obtain a separate preceptor statement from each.			
		boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the nd not attesting to the individual's "general clinical competency."			
irst Sec heck o		ring for each requested authorization:			
For 35.	<u>490:</u>				
Boa	ırd Certificatio	<u>1</u>			
Q	X I attest that	Dr. Vincenzo DeMasi has satisfactorily completed the requirements in Name of Proposed Authorized User			
		and has achieved a level of competency sufficient to function independently as an er of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.			
Train	ning and Expe	OR ience			
	I attest that	has satisfactorily completed the 200 hours of			
	rattest that	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,	<u>491:</u>				
	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.					
	Section				
For 35.	<u>690:</u>				
Boa	rd Certification				
	I attest that	has satisfactorily completed the requirements in			
	35.690(a)(1).	Name of Proposed Authorized User			
OR					
Training and Experience					
	I attest that	has satisfactorily completed 200 hours of classroom Name of Proposed Authorized User			
	and laborate experience	ory training, 500 hours of supervised work experience, and 3 years of supervised clinical n radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).			
AND					

•

PAGE 5

NRC FORM 313A (AUS)	U.S. NUCLEAR REGULAT	ORY COMMISSION
AUTHORIZED USER TRAINING AND EXPERIENCE AN	D PRECEPTOR ATTESTATION (con	tinued)
Preceptor Attestation (continued)		
Third Section		
For 35,690: (continued)		
l attest that has	received training required in 35,690(c	c) for device
operation, safety procedures, and clinical use for the ty checked below.	pe(s) of use for which authorization is s	sought, as
Remote afterloader unit(s) Teletherapy unit(s)	Gamma stereotactic radiosurge	ery unit(s)
AND		
Fourth Section		
l attest that has	achieved a level of competency suffic	cient to
achieve a level of competency sufficient to function inde	ependently as an authorized user for:	
Remote afterloader unit(s) Teletherapy unit(s)	Gamma stereotactic radiosurge	ery unit(s)
Fifth Section		
Complete the following for preceptor attestation and signatur	re:	
I meet the requirements in 10 CFR 35.490, 35.491, 35. an authorized user for:	690, or equivalent Agreement State red	quirements, as
☐ 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
Louis & Owenet in Lan Thy	302-429-6611	1/11/11
License/Permit Number/Facility Name		L
07-17418-01 Nanticoke Memorial H	iuspital	mp ⁴⁴ - Normania ya wa pamanaga ya mata kana mata ka ya ka y
	1	
		PAGE 6
		LWOE 0

• . .

STATE OF CELANARE

Day's on de professional, regulation hat size lase the

NOT PRANSFERABLE

Cancer during Suits 205 Cancer Dr. 360 1-2467

Physician M.D.

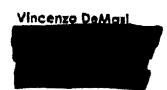
C1-0004062

ELECTATION CATE

03/31/2011

Vincenzo DeMasi

BESROOA PRIJUM



PROFESSIONAL LICENSE

IN THE PERSON NAMED IS MEMBER LICENSED TO 16... IN THE PROPESSION MODICATED ACTIVA THIS ISSUED UNDER THE LAWS OF THE STATE DE DELEWARD

Techniste substituti — 192391

Please review the information on your ticense and notify us of any changes seeded.

vision of Professional Regulation is proud of our professional and responsive customer service. Visit our web site at pridelaware 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.)



ed to change your mailing address, small address or phone number? Update your contact information online so that renewal acces and other critical mailings will reach you. (Note: This service is not available for some kinds of incenses, such as silities.)

reacw? Submit your renewal application and pay your renewal fee by credit card online. We'll send you a nutice when we'll available on our secure web site.

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

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

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

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

n't find what you need online? Just send an émail to customerservice. Ipr@state.de.us and let us know what you need.

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

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

Vincenzo DeMasi

THIS IS YOUR LICENSE CARD.

<u>):</u>

NANTICOKE MEMORIAL HOSPITAL

Initial Delineation Form

DEPARTMENT OF RADIOLOGY RADIATION ONCOLOGY

Name: VINCETEO	De	MARI	12/10/09 to 08/01/2011

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

Applicants for clinical privileges in Radiation 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

	notice de la constant		
х	Provide consultations for patients and direct course of treatment for conditions for which the patients are admitted.	V	V
х	Comprehensive evaluation of patients with cancer and related disorders	V	V)
×	Prescribe/supervise radiation therapy procedures		V,
х	Summarize/authentlcate reports		
×	Endoscopies (indirect laryngoscopy, nasopharyngoscopy, fiber optic laryngoscopy)		

p(\$107.707d)= 4	TO PER PRINTERS PROPERTY OF THE PROPERTY OF TH	readlegies. Eggingings	APTVIJEOPE S MADDIOVETIK
X	Computer tumor simulation and treatment planning		
×	Use of linear accelerator for external beam patient treatment	V	
×	Perform intraluminal, endocavllary and interstitial implants	V	
Х	Low Dose Rate (LDR) Brachytherapy	V	V

1/16/08

NANTICOKE MEMORIAL HOSPITAL

Initial Delineation Form

DEPARTMENT OF RADIOLOGY RADIATION ONCOLOGY

Name: //NCETZO DE MARCH 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.

<u>Note:</u> 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).

	Privileg 2 Privilege
	Approved the second control of the second co
X Prostate Seed Implant	
10mm	7/22/04
Signature	Date (11/16/09
Vi of X	
peparlment Chief of Radiplogy	Date
In Christa	
LCLP Chairperson	Date
\	