United States **Nuclear Regulatory Commission** Region I 475 Allendale Rd. King of Prussia, PA 19406

July 18th, 2008

Br. 1

Dr Sir or Madam,

We would like to request that Vladimir Ioffe, M.D. be added to our materials license as an authorized user. We would also like to add Palladium-103 (model - 200Link) to our radioactive materials license.

Attached: Vladimir Ioffe's CV, Maryland DOE Radioactive Material License, and American Board of Radiology Certificate.

Our License No. 07-17618-01 (30 130 60)

Sincerely,

Sandra Zorn

Director

Cancer Care Center

Nanticoke Memorial Hospital

Dandra zom

(302) 629-6611 ext. 3609

#### VLADIMIR IOFFE

5583 N. Nithsdale Drive Salisbury, MD 21801 410-591-6910 (cell) vioffe@rtsx.com

#### Education

<u>University of Maryland School of Medicine</u> 07/1997 - 05/2001 - Doctor of Medicine (M.D.)

University of Maryland Baltimore County (UMBC)

08/1993 - 05/1997 - Bachelor of Science, Biochemistry and Molecular Biology
- Non-Major Concentration in Political Science

#### Residency

Eastern Virginia Medical School
07/2002 - 06/2006 - Radiation Oncology
- Chief Resident Senior Year

Clinical Externship: University of Texas, Southwestern Medical Center 4/2006 – Stereotactic Body Radiation Therapy
- Robert Timmerman, M.D.

<u>University of Maryland Medical Center</u> 07/2001 - 06/2002 - Internship, Internal Medicine

## **Employment**

21<sup>st</sup> Century Oncology, Delmarva Region
7/2006 – Current – Physician, Radiation Oncology

## Radiation Oncology Skills

3D-Conformal Radiation Therapy (all sites), Intensity Modulated Radiation Therapy (all sites), Stereotactic Radiosurgery, Stereotactic Radiotherapy, Stereotactic Body Radiation Therapy, Prostate Brachytherapy, GYN HDR and LDR, Unsealed Sources (I-131, Sr, Sm, Zevalin, Bexxar), IGRT (orthogonal and cone beam CT), MR or PET/CT Aided Field Delineation, Conventional Simulation, CT Simulation, Interstitial Brachytherapy, Intravascular Brachytherapy, Portal Vision, EMR

#### Academic Honors

Undergraduate Education

- -Outstanding Student for the Biochemistry Department (1997)
- -Rhodes Scholar finalist (1996)
- -Scholar Athlete Award for Academic Excellence (1993-97)
- -Magna Cum Laude

#### Medical School

- -Awarded scholarship from Mayo Clinic Medical Oncology Rotation (2000)
- -Awarded scholarship from Roswell Park Cancer Institute Student Internship (1998)
- -Merit based State Delegate and State Senatorial Scholarships (1997-01)

#### Residency

- -2004 RSNA Resident Research Trainee Prize 1<sup>st</sup> Place
  -Toxicity Reduction in Breast Irradiation: Modified Irradiation Technique for Women with Large Breasts
- -2002 Maryland ACP (American College of Physicians) 2<sup>nd</sup> Place Poster Competition
  -Fetal and Ovarian Radiation Dose in Patients Undergoing Gamma Knife
  Radiosurgery

#### Non-Academic Awards

-2000 AMA Foundation Leadership Award

#### **Publications**

- 1) Ioffe V, Sandhu A, Karakla D, Wadsworth T, Mendoza A, Rao N, Dignan K, Mason E, Saadeh G, Goffman T: Prospective Single Arm Study of Radioprotection by Amifostine in High Dose Radioiodine Therapy for Thyroid Cancer. International Journal of Radiation Oncology, Biology, Physics. 2005; 63(2, Supplement 1):S147-S148. Abstract # 1002.
- 2) Miller M, <u>Ioffe V</u>, Ruffin WK, Giri S: Primary MALT Lymphoma of the Dura in a Patient with Active Scleroderma: Case Report and Literature Review. Clinical Advances in Hematology & Oncology 2004; 2(12):815-819.
- 3) <u>Ioffe V</u>, Sandhu A, Graham DW, Parker NW, Silverberg ML, Giri S: Primary Adenoid Cystic Carcinoma of the Trachea: Case Series and Literature Review. 3<sup>rd</sup> International Chicago Symposium on Malignancies of the Chest and Head & Neck, October 2004. Lung Cancer. October 2004; 46(Supplement 1):74-75.
- 4) <u>Ioffe V</u>, Miller M, Sandhu A, Neuner GA, Giri S, Koen J, Partington J, Wong P, Goffman T: Radiosurgical treatment of brain metastases in a community oncologic practice. Community Oncology 2004; 1(3):149-158.
- 5) Goffman T, <u>Ioffe V</u>, Tuttle M, Bowers JT, Mason ME: Near Lethal Respiratory Failure after rhTSH in a Patient with Metastatic Thyroid Carcinoma. Thyroid 2003; 13(8):827-830.
- 6) <u>Ioffe V</u>, Hudes RS, Shepard D, Simard JM, Chin LS, Yu C: Fetal and Ovarian Radiation Dose in Patients Undergoing Gamma Knife Radiosurgery. Surgical Neurology 2002;58:32-41.

7) Balcer-Kubiczek E.K., Zhang XF, Han LH, Harrison GH, Davis CC, Zhou XJ, <u>Ioffe V</u>, McCready WA, Abraham JM, and Meltzer SJ. BIGEL analysis of gene expression in HL60 cells exposed to X rays or 60 Hz magnetic fields. Radiation Research 1998 Dec; 150(6):663-72

#### Presentations

1) The 4<sup>th</sup> S. Takahashi Memorial International Workshop on 3D-CRT The Nagoya Congress Center; Nagoya, Japan Poster Presentation, December 10-12, 2004 Title: Dosimetric Comparison of Three-Dimensional Conformal Radiation Therapy (3D-CRT) vs. Intensity Modulated Radiation Therapy (IMRT) in Head & Neck Cancer

2) 2004 Annual RSNA meeting, Chicago Illinois
Oral Presentation, December 3, 2004
Title: Toxicity Reduction in Breast Irradiation: Modified Irradiation Technique for
Women with Large Breasts

3) 2004 Annual RSNA meeting, Chicago Illinois Oral Presentation, November 29, 2004 Title: Radiosurgical Treatment of Brain Metastases in a Community Oncologic Practice

4) 2004 3rd Intern. Chicago Symposium on Malignancies of the Chest and Head & Neck Poster presentation, October 7-9, 2004
Title: Primary Adenoid Cystic Carcinoma of the Trachea: Case Series and Literature Review

5) 2002 Annual Meeting of the Maryland ACP (American College of Physicians)
Poster presentation
Title: Fetal and Ovarian Radiation Dose in Patients Undergoing Gamma Knife
Radiosurgery

6) 2001 Annual RSNA meeting, Chicago, Illinois
Poster presentation
Title: Fetal and Ovarian Radiation Dose in Patients Undergoing Gamma Knife
Radiosurgery

### Leadership Activities

#### Organized Medicine

- -Vice-President MedChi (MD State Medical Society) Students' Section (2000-2001)
- -Baltimore City Medical Society Board of Directors (1998-2002)
- -MedChi Membership Committee (1998-2002)
- -MedChi AMA Delegation (1999-2000)
- -Maryland State Chair AMA-Medical Student's Section (1999-2000)
- -President of the St. George's Cancer Society

#### Activism

- -Authored resolution on prevention of smoking among young adults (2000)
- -The resolution was passed by the MedChi House of Delegates creating a new state medical policy (1/2001)
- -Wrote an amendment to a State Senate bill and defended the amendment with testimony in the Economic and Environmental Affairs Committee (State Senate) on behalf of MedChi and Smoke-Free MD (3/2001)
- -Provided testimony to the Governor's Taskforce on Smoking Cessation
- -Lobbied Maryland Congressional Representatives and State General Assembly Representatives to support public health and patient advocacy bills

#### Athletic Extracurricular Activities

- -University of Maryland Varsity Tennis (1993-1997)
- -Medical school basketball team (1997)

## Volunteer Experience

- -Prostate cancer screening, Sentara Cancer Centers (2004)
- -VNA Hospice (2/98-2000)

#### Certification

United States Medical Licensing Examination
Step I - June, 1999 - Passed
Step II - August, 2000 - Passed
Step III - June, 2002 - Passed

American Board of Radiology (Radiation Oncology)
June 5, 2007 - Board Certified in Radiation Oncology

## Professional Memberships

ASTRO, American Society for Therapeutic Radiation Oncology ASCO, American Society of Clinical Oncology AMA, American Medical Association MedChi, Maryland State Medical Society RSNA, Radiologic Society of North America ACRO, American College of Radiation Oncology



## Hobbies

-Racquet sports; jogging; cycling; fantasy football

## Second Language -Fluent in Russian

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## 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.

2 Tiennes No.

2. Address:	804 Snow Hill Road Salisbury, Maryland 21804		4. Amendment Number:		NEW (Code 02301)
			5. Expiration	Date:	A <u>pril</u> 30, 2015
6. Radioactiv mass numi	e material element & let:	7. Chemical and/or	physical form:	radioec	um amount of stivity which licensee may at any one time:
A. Palladium- B. Iodine - 12 C. Cosium-13	5	A. Sealed Sources B. Sealed Sources C. Sealed Sources		A. 400 ml B. 400 mi C. 400 mi	llicuries
	<del></del>	Ŧ#	A101	<u> </u>	

#### License Conditions

### 9. Authorized Use(s):

- A. Brachytherapy. Permanent interstitial implant for treatment of cancer in humans.
- B. Brachytherapy. Pennanent interstitial implant for treatment of cancer in humans.
- C. Brachytherapy. Permanent interstitial implant for treatment of cancer in humans.
- 10. The authorized place of use is the licensee's address stated in Item 2. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address.
- 11. A. The radiation protection program shall be under the supervision of Vladimir laffe, M.D..
  - B. Radioactive material shall be used by or under the supervision of Mark Sobezak, M.D., Vladimir loffe, M.D., Manoj Jain, M.D., and Scott Edwards, M.D.
  - C. Radioactive material shall be administered to, or removed from humans by Mark Sobczak, , M.D., Vladimir Ioffe, M.D., Manoj Jain, M.D., and Scott Edwards, M.D.
  - D. Medical Physicists authorized on this license are: Xudong Chen, M.S. and Sarkar Chakravorty, Ph.D.
- 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.

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## RADIÓLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

Page 2 of 4

Licenso No.:

MD-45-025-01

Amendment Number: NEW CODE 02301

#### License Conditions, Continued

- 13. This condition is specific to the applicant's initial receipt of this license. The licensee shall notify the Radiological Health Program's Inspection and Compliance Division, in writing, no later than 10 calendar days after initial receipt of radioactive material authorized on this license.
- 14. Bach 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 dontamination at intervals not to exceed six (6) months. In the absence of a partificate 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 thight have been damaged, or might be leaking, it shall be tested for leakage before further use.
  - B. 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 scaled source or from the surfaces of a device in which the sealed source is permanently mounted or stored on which one might expect dontamination to accumulate.
  - Records of leak tests shell be kept in units of microcuries and maintained for inspection by the C. Department
  - If the test reveals the presence of 0.005 microcuries of more of removable contamination, the D. censee aball immediately withdraw the sealed source from use and shell cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A eport shall be filed within five (5) days of the test with the Administrator, Radiological Health Brogram, 1800 Washington Boulevard, Baltimore, Maryland 21230, describing the equipment involved, the test results, and the corrective action taken.
  - Notwithstanding the periodic leak test required by this condition, any licensed sealed source is E. exempt from such leak tests when the source contains 100 microcuries or leas of beta and/or damma emitting material or 10 microcuries or less of alpha emitting material.
  - est for leakage and/or contamination shall be performed by licensee or by other persons F. pecifically authorized by the Department, the U.S. Nuclear Regulatory Commission or another greenent State to perform such services.
  - Except for alpha sources, the periodic leak test required by this condition does not apply to sealed G. 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 transfor.
- Sealed sources containing radioactive material shall not be opened. 15.
- Radioactive material in brachytherapy sources shall be administered to and removed from human patient 16. only by an authorized physician.

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Department of the Environment

# RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

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License No.:

NID-45-025-01

Amandmant Number: NEW CODE 02301

#### License Conditions, Continued

- 17. Patients containing therapeutic implants of Iodine-125, Palladium-103 or Cesium-131 shall be released from the hospital using criteria contained in USNRC Regulatory Guide 8.39.
- 18. The licensee shall conduct a physical inventory every three (3) months to account for all scaled sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Department, and shall include the quantities and kinds of radioactive material, location of scaled sources, and the date of the inventory.
- 19. Food and beverage containers shall not be discarded in radioactive or normal treah containers in licensee's areas utilizing radioactive materials.
- 20A. 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 of practices. Additionally, the licensee shall not falsify, tamper with, or rander inaccurate any monitoring device of method.
- 20B. Violation of any term, condition, or regulation could subject the heensee to administrative or civil penalty of criminal presecution, as specified in Title 8, Radiation, of the Article Environment of the Annotated Code of Maryland.
- 21. The licensee 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.

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Department of the Environment

## RADIOLOGICAL HEALTH PROGRAM RADIOACTIVE MATERIAL LICENSE

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License No.

MID-45-025-01

Amendment Number: NEW CODE 02301

#### License Conditions, Continued

- Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive 22, material authorized by this license in accordance with statements representations and procedures contained in:
  - Application dated October 19, 2007
  - Letter with attachments dated March 21, 2008. 2.
  - Faceimile dated April 10, 2008

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

April 11, 2008

NAO

Robert H. Holder Roland G. Fletcher, Manager III Radiological Health Program

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, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

## Pladimir Ioffe, MP

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 fifth day of June, 2007
Thereby demonstrating to the satisfaction of the Board that he is qualified to practice the specialty of

AM Tligible



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Radiation Oncology

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Certificate No. 55079

Malid through 2017

This is to acknowledge the receipt of	of your letter/application dated
includes an administrative review h	C) 7-17618-01 hissions. Your application was assigned to a that the technical review may identify additional
Please provide to this office with	nin 30 days of your receipt of this card
	warded to our License Fee & Accounts Receivable ately if there is a fee issue involved.
Your action has been assigned <b>Ma</b> When calling to inquire about this a You may call us on (610) 337-5398	ction, please refer to this control number.
NRC FORM 532 (RI) (6-96)	Sincerely, Licensing Assistance Team Leader